Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0371506	01/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Macomb Medical Clinic Pc	2405 E 14 Mile Road, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Laboratory Director, Office Administrator, and the Office Manager, the laboratory failed to report SARS-CoV-2 test results every day of patient testing for 99 of 99 days reviewed from June 19, 2020 to January 18, 2021. Findings include: 1. SARS-CoV-2 "Accession Log" documentation was reviewed from June 19, 2020 to January 18, 2021. 2. No documentation of SARS-CoV-2 test result reporting from June 19, 2020 to January 18, 2021. 3. No documentation of test reporting revealed for 1403 SARS-CoV-2 tests, 701 IgG and 702 IgM, were reported as required. 4. The Laboratory Director, Office Administrator, and the Office Manager confirmed the findings on 1/21/2021 at 4:57 pm.
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 lack of documentation and interview with the Office Manager (OM), the laboratory failed to retain documentation for the reporting activity of the COVID-19 IgG/IgM results to the healthcare provider for 99 (6/18/20 to 1/18/21) of 99 days of testing. Findings include: 1. No documentation was available on the day of the survey to show positive and negative COVID-19 IgG/IgM results had been transmitted to the healthcare provider for 99 (6/19/20 to 1/18/21) of 99 days of testing. 2. A interview on 1/21/21 at 9:23 am, the OM confirmed the laboratory did not retain documentation of the COVID-19 test results that were faxed to the healthcare provider.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, 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 document review and interview, the laboratory failed to meet Immunology requirements. Findings include: 1. The laboratory failed to establish a policy and procedure for reporting patient results for the COVID IgG/IgM Rapid Test Cassette testing to the healthcare provider. Refer to D5403. 2. The laboratory failed to establish performance specifications for COVID-19 IgG/IgM Rapid Test Cassette testing before reporting patient test results. Refer to D5421. 3. The laboratory failed to perform control procedures for the Covid-19 IgG/IgM testing each day of patient testing. Refer to D5445. 4. The laboratory failed to establish a system to routinely check the transmission of COVID-19 IgG/IgM testing to the healthcare provider. Refer to D5801.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform control procedures each day of patient testing for the endocrinology prostate specific antigen (PSA). Refer to D5445. 2. The laboratory failed to run the "FREND System Quality Control (QC) Cartridge" every day of patient testing. Refer to D5445.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to establish a policy and procedure for reporting patient results for the COVID-19 IgG/IgM Rapid Test Cassette testing for 99 (6/19/20 to 1/18/21) of 99 days of testing. Findings include: 1. A record review revealed the laboratory did not establish a policy and procedure for reporting all positive and negative COVID-19 IgG/IgM testing to the healthcare providers for 99 (6/19/20 to 1/18/21) of 99 days of testing. 2. A record review of the "Communicable Disease" manual under the tab labeled "Covid-19" the following was written on the tab page "Fax positive IgM antibody to Macomb County Health Dept Communicable Disease 586-493-0075." 3. When queried on 1/21 /21 at 9:23 am, the OM stated the office started sending all results to the healthcare provider in March 2021, then they were instructed to stop (no date given), then only positive IgM test reports were sent (no date given), and now no results are being sent to the healthcare provider. 4. A interview on 1/21/21 at 9:23 am the OM confirmed the laboratory did not establish and follow a policy and procedure for the reporting of COVID-19 testing to the healthcare provider.
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 (TC) #2, the laboratory failed to establish performance specifications for COVID-19 IgG/IgM Rapid Test Cassette testing before reporting patients for 2 (6/19/20 and 6/22/20) of 99

	days of testing. Findings include: 1. A record review of the laboratory's patient "Accession Log" revealed the laboratory was performing COVID-19 IgG/IgM testing for 2 (6/19/20 and 6/22/20) of 99 days prior to performance specification were documented. 2. A record review revealed that 47 tests, 23 IgG and 24 IgM, were reported out. 3. An interview on 1/21/2021 at approximately 10:00 am, TC2 confirmed the laboratory did not verify performance specifications for the COVID-19 IgG/IgM testing before reporting patients.
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 Technical Consultant (TC) #2 and Testing Personnel #1 (TP1), the laboratory failed to perform control procedures each day of patient testing for the endocrinology prostate specific antigen (PSA) for 2 (#2 and #10) of 11 patient charts audited from January 2020 to present date. Findings include: 1. A record review for 2 (#2 and #10) of 11 patient charts audited revealed the PSA external quality control was not performed on the day of testing. 2. On 1/21 /21 at approximately 4:30 pm when queried, TP1 informed the surveyor that external quality control is only run monthly or whenever a new testing kit is received. 3. A interview on 1/21/21 at approximately 4:30 pm with TC2 and TP1 confirmed two different levels of external controls had not been performed each day of patient testing and that an individualized quality control plan (IQCP) had not been implemented to decrease the number and frequency of running the external controls. B. Based on lack of documentation and interview with Technical Consultant (TC) #2 and Testing Personnel #1 (TP1), the laboratory failed to run the "FREND System Quality Control (QC) Cartridge" every day of patient testing for 2 (January 21, 2019 to January 21, 2021) of 2 years of testing. Findings include: 1. Record review of the "NanoEnTek FREND Prostate Specific Antigen (PSA) PLUS" manufacturer's instructions states: "FREND QC Cartridge contains multiple controls to check optic part of the system. By testing QC Cartridge, part of analytical components of the system of (1) laser power, (2) alignment, and (3) mechanical integrity are confirmed. Each day of patient testing, perform QC Cartridge testing." 2. No documentation was found to show the QC Cartridge had been performed. 3. When queried on 1/21/2021 at approximately 4: 20 pm, TP1 stated, "she did not run the cartridge." 4. A interview on 1/21/2021 at 4:30 with TC2 and TP1 confirmed the QC Cartridge was not performed and documented each day of patient testing. C. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to perform control procedures for the Covid-19 IgG/IgM testing each day of patient testing for 9 (#1 - #9) of 9 patient charts audited during the 7 months of testing. Findings include: 1. A record review for 9 (#1 - #9) of 9 patient charts audited revealed 2 levels of external quality control was not performed on the day of testing as follows: a. chart audit #1 - #6 no positive or negative controls documented b. chart audit #7 - #9 no negative control documented

	2. Record review of the Instruction for Use (IFU) for the Healgen COVID-19 IgG /IgM Rapid Test Cassette states under the Quality Control section: "Control standards are not supplied with this kit, however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance." 3. A interview on 1/21/21 at 12:05 with TP1, confined that external positive and negative controls were not run each day of patient testing.
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 Consultant (TC) #2, the laboratory failed to establish a system to ensure the Laboratory Information System (LIS) calculated the Risk Factor (lipid/cardiac) was monitored for accuracy from the point of entry to the final patient's electronic medical record (EMR) for 2 (January 21, 2019 to January 21, 2021) of 2 years. Findings include: 1. A record review for miscellaneous calculations revealed for 2 (January 21, 2019 to January 21, 2021) of 2 years the laboratory had no documentation to show the LIS calculated chemistry Risk Factor (lipid/cardiac) was being monitored for accuracy from the point of entry to the final patient's EMR report. 2. A interview on January 21, 20121 at 11:04 am, TC2 confirmed the Risk Factor (lipid/cardiac) calculation was not checked for accuracy. B. Based on lack of documentation and interview with the Office Manager (OM), the laboratory failed to establish a system to routinely check the transmission of COVID-19 IgG/IgM testing to the healthcare provider for 99 (6/19/20 to 1/18/21) of 99 days of testing. Findings include: 1. No documentation of the transmission of positive and /or negative COVID-19 IgG/IgM testing to the healthcare provider were available. 2. When queried on 1/21/21 at approximately 9:23 am, the OM was not able to provide the requested documentation for the surveyor to review. 3. A interview on 1/21/21 at approximately 9:23 am, the OM confirmed that a system was not established to routinely check the transmission of COVID-19 testing to the healthcare provider.