Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0371506	05/21/2024
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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure positive patient identification through the testing process (refer to D5203) and the laboratory failed to follow its competency assessment policy (refer to D5209).
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 Consultant, the laboratory failed to ensure positive patient identification through the testing process for 1 (Patient #4) of 7 patient test records reviewed. Findings include: 1. A review of the laboratory's patient test records revealed Patient #4 had Free T4 testing ordered on 3 /17/23, performed on 3/20/23, and was assigned the sample number of "97493." 2. A

	review of the laboratory's FREND immunoassay instrument data from 3/20/23 revealed a lack of results for the sample number 97493. Results for sample number 97456, a sample number not on the testing log, were present with a Free T4 result of "1.06 ng/dL." 3. A review of the Patient #4's test report showed Free T4 results from 3 /20/24 reported on 3/21/24 as "1.0 ng/dL." 4. An interview on 5/21/24 at 2:51 pm revealed the Technical Consultant acknowledged the sample number discrepancy listed above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow its competency assessment policy for 1 (Coverage Testing Personnel) of 3 laboratory testing personnel. Findings include: 1. A review of the laboratory's records revealed a lack of quality control results for Total Iron Binding Capacity (TIBC) documentation on 7/17/23. 2. When asked on 5/21/24 at 3:05 pm about the missing quality controls from 7/17/23, Testing Personnel #1 revealed they were on vacation during this timeframe and had another person cover for them. 3. An interview on 5/21/24 at 3:08 pm with the Technical Consultant revealed they were unaware the Coverage Testing Personnel was performing testing during this time and that testing performed by the Coverage Testing Personnel was against the competency assessment policy of the laboratory.
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: . Based on observation, record review, and interviews, the laboratory failed to ensure diluent for the Medonic M-Series Complete Blood Count (CBC) analyzer was labeled with expiration dates (refer to D5415), failed to ensure reagents were not used beyond the expiration date (refer to D5417 A), failed to ensure blood collection tubes were not used beyond expiration dates (refer to D5417 B), failed to verify performance specifications for Vitamin D and Thyroid Stimulating Hormone (TSH) testing using the NanoEnTek Frend Immunoassay analyzer prior to testing patient specimens (refer to D5421), failed to conduct a risk assessment supporting the number and frequency of control procedures in the laboratory's Quality Control Plan (refer to D5425), failed to ensure the electronic quality control laser check for the NanoEnTek Frend

	Immunoassay analyzer was within limits before reporting patient results (refer to D5431), and failed to perform at least two levels of control materials for glucose testing (refer to D5447).
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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) 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 #1, the laboratory failed to ensure diluent for the Medonic M-Series Complete Blood Count (CBC) analyzer was labeled with expiration dates for seven urine collection cups observed. Findings include: 1. The surveyor observed seven urine cups in the laboratory with "Diluent" written on the top of the orange cap on 5/21/24 at 9:35 am. 2. An interview on 5/21/24 at 9:35 am with Testing Personnel #1 revealed they did not know how often the diluent in the cups are changed and confirmed expiration dates were not listed on the cups containing the diluent.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . A. Based on observation and interview with the Technical Consultant, the laboratory failed to ensure reagents were not used beyond the expiration date for 3 bottles of reagent observed. Findings include: 1. The surveyor observed expired reagents in the laboratory on 5/21/24 at 9:45 am: a. 1 bottle of Acetone with the expiration date of 11 /04/2021. b. 1 bottle of Cholesterol Reagent with the expiration date of 12/31/2023. c. 1 bottle of Iron Buffer Reagent with expiration date of 04/30/2024. 2. An interview with Techincal Consultant at 9:45 am confirmed the bottles listed above were expired. B. Based on observation and interview with the Technical Consultant, the laboratory failed to ensure blood collection tubes were not used beyond expiration dates for 5 lavender top vacutainer tubes observed. Findings include: 1. The surveyor observed 5 expired lavender top tubes at 10:07 am in a phlebotomy draw tray with an expiration date of 10/31/2019 for 1 tube and 12/31/2019 for 4 tubes. 2. An interview with the Technical Consultant on 5/21/24 at 10:08 am confirmed the expiration date of the lavender top tubes.
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 Consultant, the laboratory failed to verify performance specifications for Vitamin D and Thyroid Stimulating Hormone (TSH) testing using the NanoEnTek Frend Immunoassay analyzer prior to testing patient specimens for 6 (November 2023 to May 2024) of 6 months since the test systems were introduced. Findings include: 1. A record review of the Vitamin D verification of performance specification data from 11/7/23 to 11/15/23 revealed "QC failed" for laser check on on instrument tape indicating the test system was not performing correctly. 2. A record review of the TSH verification of performance specification data from 11/15/23 to 12/7/23 revealed "QC failed" for laser check indicating the test system was not performing correctly. 3. A review of the laboratory's "Frend Vitamin D" and "Frend TSH" manufacturer's instructions for use revealed a section titled "Quality Control" stating, "The FREND QC Cartridge contains multiple controls that check the optics of the system. By testing the QC Cartridge, the integrity of the laser power, alignment and mechanical components of the system are confirmed." 4. An interview on 5/21/24 at 11:30 am with the Technical Consultant confirmed the laser checks had failed during runs used to verify the performance specifications of Vitamin D and TSH testing and corrective action was not performed prior to initiating patient testing.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to conduct a risk assessment supporting the number and frequency of control procedures in the laboratory's Quality Control Plan for 3 (Vitamin D, Thyroid Stimulating Hormone, and Free Thyroxine) of 4 assays performed using the NanoEnTek Frend Immunoassay analyzer. Findings include: 1. A review of the laboratory's Individualized Quality Control Plans for Vitamin D, Thyroid Stimulating Hormone, and Free Thyroxine revealed a lack of risk assessments to support the laboratory's Quality Control Plan of performing external control procedures "every 30 days, with every new lot of cartridges, when there is a question of system/cartridge integrity, or when a new staff member is being trained." Risk assessments did not include data evaluating the stability of the test system for at least 30 days. 2. An interview on 5/21/24 at 11:30 am with the Technical Consultant confirmed documentation showing the laboratory's risk assessments supported the Quality Control Plans for Vitamin D, Thyroid Stimulating Hormone, and Free Thyroxine were not available.
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 record review and interview with the Technical Consultant, the laboratory failed to ensure the electronic quality control laser check for the NanoEnTek Frend Immunoassay analyzer was within limits before reporting patient results for 16 (11/2 /23 to 12/15/23) patient testing dates reviewed. Findings include: 1. A review of the laboratory's "Quality Control Plan PSA Vitamin D TSH" revealed a section stating, "An electronic quality control is run each day of testing upon startup to check calculation ration, laser power, alignment and overall mechanical integrity" and "If either electronic or external control fail to pass patients cannot be run until trouble shooting is performed and both controls pass." 2. A review of the laboratory's NanoEnTek electronic quality control (EQC) laser function checks revealed failed EQC for the following patient testing dates: a. 11/2/23 b. 11/6/23 c. 11/7/23 d. 11/10 /23 e 11/13/23, one patient received two PSA tests: one with a result of 5.22 ng/mL and the other with a result of 5.87 ng/mL. The result reported was 5.55 ng/mL. f. 11/16 /23 g. 11/20/23 h. 11/21/23 i. 11/27/23 j. 11/28/23 k. 12/4/23 l. 12/6/23 m. 12/8/23 n. 12/11/23 o. 12/13/23 p. 12/15/23 3. Interview with Technical Consultant on 5/21/24 at 12:00 pm revealed Total patients reported when EQC failed includes 27 PSA patient tests, 65 Free Thyroxine patient tests and 97 Vitamin D patient tests.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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 Consultant, the laboratory failed to perform at least two levels of control materials for glucose testing for 1 (10/14 /22) of 7 patient testing dates reviewed. Findings include: 1. A record review of quality control documentation revealed glucose testing performed using the Pointe 180 analyzer had one control (Low Level) documented on 10/14/22 and no second level of control performed. 2. A review of the 10/14/22 patient testing log for glucose testing revealed a total of five patients received glucose testing on 10/14/22. 3. An interview with Technical Consultant on 5/21/24 at 2:13 pm confirmed the laboratory failed to include at least two control materials for glucose testing on 10/14/22.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to include the laboratory name address where testing was performed for 7 of 7 patient test reports reviewed. Findings include: 1. A record review of 7 patient test reports from May 2022 to May 2024 revealed a lack of laboratory name and address. 2. An interview was conducted with Technical Consultant at 4:25 pm and confirmed lack of laboratory name and address on patient test reports.
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 observations, record review, and interviews, the Laboratory Director failed to ensure performance specifications were verified for Vitamin D and Thyroid Stimulating Hormone (TSH) testing using the NanoEnTek Frend Immunoassay analyzer prior to testing patient specimens (refer to D6086), failed to ensure risk assessments performed supported the number and frequency of control procedures in the laboratory's Quality Control Plan (refer to D6093 A), failed to ensure at least two levels of control materials were performed for glucose testing each date of patient testing (refer to D6093 B), failed to ensure the electronic quality control laser check for the NanoEnTek Frend Immunoassay analyzer was within limits before reporting patient results (refer to D6097), failed to ensure testing personnel received appropriate training for hematology, endocrinology, and chemistry laboratory testing and had demonstrated the ability to provide and report accurate results (refer to D6102 A), and failed to ensure testing personnel performing high complexity testing were qualified (refer to D6102 B).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure performance specifications were verified for Vitamin D and Thyroid Stimulating Hormone (TSH) testing using the NanoEnTek Frend Immunoassay analyzer prior to testing patient specimens. 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 risk assessments performed supported the number and frequency of control procedures in the laboratory's Quality Control Plan. Refer to D5425. B. Based on record review and interview, the Laboratory Director failed to ensure at least two levels of control materials were performed for glucose testing each date of patient testing. Refer to D5447.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure the electronic quality control laser check for the NanoEnTek Frend Immunoassay analyzer was within limits before reporting patient results. Refer to D5431.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . A. Based on record review and interviews, the Laboratory Director failed to ensure testing personnel received appropriate training for hematology, endocrinology, and chemistry laboratory testing and had demonstrated the ability to provide and report accurate results for 1 (Coverage Testing Personnel) of 3 testing personnel. Findings include: 1. A review of the laboratory's records revealed a lack of quality control results for Total Iron Binding Capacity (TIBC) documentation on 7/17/23. 2. When asked on 5/21/24 at 3:05 pm about the missing quality controls from 7/17/23, Testing Personnel #1 revealed they were on vacation during this timeframe and had another person cover for them. 3. An interview on 5/21/24 at 3:08 pm with the Technical Consultant revealed they were unaware the Coverage Testing Personnel was performing testing during this time and no training documentation was available. B. Based on record review and interviews, the Laboratory Director failed to ensure testing personnel performing high complexity testing were qualified. Refer to D6171.

D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interviews, the laboratory failed to ensure testing personnel performing high complexity testing were qualified (refer to D6171) and the Testing Personnel failed to ensure positive patient identification through the testing process (refer to D6173).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for

	performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure testing personnel performing high complexity testing were qualified for 1 (Coverage Testing Personnel) of 3 testing personnel. Findings include: 1. A review of the laboratory's records revealed a lack of quality control results for Total Iron Binding Capacity (TIBC) documentation on 7/17/23. 2. When asked on 5/21/24 at 3:05 pm about the missing quality controls from 7/17/23, Testing Personnel #1 revealed they were on vacation during this timeframe and had another person cover for them. 3. The surveyor requested documentation showing the Coverage Testing Personnel qualified to perform high complexity testing on 5/21/24 at 3:08 pm and it was not made available. 4. The laboratory was given an additional 7 days to provide the missing documentation and it was not received.
D6173	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495 The testing personnel are responsible for specimen processing, test performance and for reporting test results. This STANDARD is not met as evidenced by: Based on record review and interview, the Testing Personnel failed to ensure positive patient identification through the testing process. Refer to D5203.