Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0365956	02/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Steven D Trombly Md	5195 15 Mile Rd, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . A. Based on record review, observation, and interview with the Technical Consultant (TC), the laboratory failed to follow its policy for specimen labeling for 3 (2 blood tubes and 1 urine specimen) specimens observed in the laboratory. Findings include: 1. A review of the laboratory's "Specimen Rejection Criteria" policy revealed a section stating, "Specimen must be properly labeled with: Patient Name and Date of Birth." 2. The surveyor observed the following specimens during a tour of the laboratory on 2/9/22 at 10:49 am: a. Two EDTA blood tubes with a sticker indicating the patient's name and full address. b. One urine cup with "G" on the lid. 3. An interview on 2/9/22 at 2:00 pm with the TC confirmed the laboratory had not followed their specimen labeling policy. B. Based on record review, observation, and interview with Testing Personnel #1 (TP1), the laboratory failed to follow its policy for specimen acceptability and rejection for 1 urine specimen observed in the laboratory. Findings include: 1. A review of the laboratory's "Urine Specimen Procedure" revealed a section stating, "Collection containers must be clean and made of inert disposable plastic. Do not reuse containers. Containers should have a capacity of 50 to 100 mL with a round opening at least two inches in diameter." and "Sterile containers with lids and no preservatives are required if the specimen is to be used for microbiological studies." 2. A review of the laboratory's "Specimen Rejection Criteria" revealed a section stating, "Specimen must be collected in designated tube or

	container with proper anticoagulant, preservative or sterility." 3. The surveyor observed a small, clear plastic food container with a "G" on the lid containing a yellow liquid in the laboratory's refrigerator on 2/9/22 at 11:03 am. 4. An interview on 2/9/22 at 11:03 am with TP1 confirmed the contents of the container was patient urine, the specimen was not collected in the correct specimen container, and the specimen had not been rejected.
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 and document calibration procedures when calibration verification failed to meet the laboratory's acceptable limits. Refer to D5437. 2. The laboratory failed to perform calibration verification at least every 6 months. Refer to D5439. 3. The laboratory failed to perform corrective action for all patient test results obtained since the last acceptable calibration for B-type natriuretic peptide (BNP) testing when it was discovered the calibration was not acceptable. Refer to D5783.
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 with the Technical Consultant (TC), the laboratory failed to perform and document monthly cleaning for the laboratory's Medonic hematology analyzer for 3 (August 2021 to October 2021) of 24 months reviewed. Findings include: 1. A review of the laboratory's "Medonic M-Series Hematology Analyzer" maintenance documents revealed a lack of documented monthly cleaning for August, September, and October 2021. 2. An interview on 2/9 /22 at 12:20 pm with the TC confirmed monthly cleaning was not performed and documented.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform calibration verification when calibration verification failed to meet acceptable limits for 1 (High-Density Lipoprotein) of 11 analytes on the laboratory's test menu requiring calibration verification testing. Findings include: 1. A review of the laboratory's calibration verification documentation for its High-Density Lipoprotein (HDL) testing performed on 1/26/22 revealed the testing did not show the test was linear. 2. The surveyor requested documentation of the corrective action for the failed calibration verification event on 2/9/22 at 11:29 am and it was not made available. 3. An interview on 2/9/22 at 2:00 pm with the TC confirmed the laboratory had not performed calibration verification testing after HDL had failed its calibration verification and the laboratory performed HDL testing on 89 patients since 1/26/22.
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 with the Technical Consultant (TC), the laboratory failed to perform calibration verification testing at least every 6 months for C-Reactive Protein (CRP) analyte for 2 (February 2020 to February 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's calibration verification documentation revealed a lack of documentation for CRP calibration verification between February 2020 to February 2022. 2. A review of the laboratory's "Calibration Verification" policy revealed a section stating, "Calibration verification will be

	performed every six months. Calibration verification will be performed on all analytes that have less than a three point calibrator." 3. An interview on 2/9/22 at 11:32 am with the TC confirmed CRP did not have a three-point calibration and calibration verification had not been performed.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform corrective action for all patient test results obtained since the last acceptable calibration for B-type natriuretic peptide (BNP) testing when it was discovered the calibration was not acceptable during a proficiency testing event for 1 (1st event 2021) of 6 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing reports revealed the laboratory obtained a 0% for its BNP testing during the first testing event of 2021. The laboratory's corrective action indicated a new calibration was performed and the repeated samples fell within the specified ranges. 2. The surveyor requested the corrective action for patients that had testing performed during the time the unacceptable calibration was in use for the proficiency testing failure investigation on 2/9/22 at 10:12 am and it was not made available. 3. An interview on 2/9/22 at 10:12 am with the TC confirmed the laboratory did not perform corrective action for patients that had BNP testing during the time the unacceptable calibration was in use during the proficiency testing failure investigation.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the Laboratory Director failed to ensure an approved corrective action plan was followed when proficiency testing results were unacceptable for 1 (3rd Event 2021) of 6 events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory received a score of 50% for its Ferritin testing during the 3rd event of 2021. The results were reviewed by the TC on 11/30/21. 2. The surveyor requested documentation of corrective action for

	the proficiency testing event on 2/9/22 at 9:56 am and it was not made available. 3. An interview on 2/9/22 at 9:56 am with the TC confirmed corrective action had not been performed for Ferritin testing when the proficiency testing results were found to be unacceptable.