Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0371580	02/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Heights Medical Center	11600 15 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
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: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to perform control procedures for hematology testing for 2 days (3/5/2019 and 3/8/2019) of 20 months reviewed. Findings include: 1. A record review of the laboratory's "Hematology Log" revealed hematology testing was performed on patients for the following days: a. 3/5/2019, 5 patients were tested. b. 3/8/2019, 7 patients were tested. 2. A review of the laboratory's hematology quality control records revealed a lack of quality control documentation for 3/5/2019 and 3/8/2019. 3. An interview on 2/18/2020 at 12:23 pm with TC1 confirmed no quality control was performed for hematology testing for the dates listed above.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if

	applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to maintain a duplicate of the original report along with the corrected report for 1 (Patient #17) of 20 patient charts audited. Findings include: 1. A review of the laboratory's established procedure manual revealed a section stating, "The laboratory technician will be notified when a lab error is found. The technician will then correct the error and initial the report form. The ordering physician will then be notified and he will also initial the report form. All errors will be described on the lab error report form and the records will be saved for two years." 2. An audit of 20 patient charts revealed Patient #17 had a lipid and liver panel report dated 12/30/19 that contained white-out in the date of birth section of the report, hiding the original report. 3. An interview on 2/18/2020 at 9:16 am with TC1 confirmed the original report was not available for Patient #17.
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 Technical Consultant #1 (TC1), the laboratory director failed to ensure a corrective action plan was followed when proficiency testing results were found to be unacceptable or unsatisfactory for 2 (first event 2018 and second event 2019) of 6 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records revealed the following events had less than 100%: a. First event 2018 hematocrit and erythrocytes both had a score of 80% b. Second event of 2019 was self-evaluated and the hematocrit had a score of 40% 2. The surveyor requested corrective action on 2/18/2020 at 11:16 am for the testing events listed above and they were not made available. 3. An interview on 2/18/2020 at 11:16 with TC1 confirmed corrective action was not available for the proficiency testing events listed above.