Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D0371579	**(X3) Date Survey Completed** 02/06/2024
Name of Provider or Supplier Sterling Medical Center, Pllc	**Street Address, City, State** 13409 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**
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Testing Personnel, the laboratory failed to establish safety procedures for its toxicology testing laboratory for 5 (October 2023 to February 2024) of 5 months since the laboratory started testing. Findings include: 1. The surveyor observed the laboratory on 2/6/24 at 9:09 am and noticed lack a of eyewash station present. 2. An interview on 2/6/24 at 9:31 am with the Testing Personnel revealed the laboratory started patient testing in October 2023. 3. A review of the laboratory's policies and procedures revealed a lack of safety procedures. 4. An interview on 2/6/24 at 9:50 am with the Testing Personnel revealed the laboratory had not established safety procedures.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, 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 observation, record review, and interviews, the laboratory failed to establish competency assessment policies and procedures to assess Clinical Consultant, Technical Consultant, and Testing Personnel competency (refer to

	D5209), failed to establish written policies and procedures to include specimen collection, labeling, storage and preservation, acceptability and rejection, and specimen referral (refer to D5311), failed to establish written test procedures (refer to D5401), failed to ensure quality control materials and wash solution were not used when expiration dates were exceeded (refer to D5417), failed to verify the acceptability criteria for urine toxicology control materials (refer to D5469), failed to perform corrective action for patients receiving urine toxicology testing when quality control testing was out of range (refer to D5783), and failed to include a second patient identifier, units of measurement, and reference ranges used for interpretation on the test report (refer to D5805).
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 interview with the Testing Personnel, the laboratory failed to establish competency assessment policies and procedures to assess Clinical Consultant, Technical Consultant, and Testing Personnel competency for 5 (October 2023 to February 2024) of 5 months since the laboratory started testing. Findings include: 1. An interview on 2/6/24 at 9:31 am with the Testing Personnel revealed the laboratory started patient testing in October 2023. 2. A review of the laboratory's policies and procedures revealed a lack of competency assessment policies and procedures to assess the competency of its Clinical Consultant, Technical Consultant, or Testing Personnel. 3. An interview on 2/6/24 at 9:50 am with the Testing Personnel revealed the laboratory had not established competency assessment policies or procedures.
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: . Based on record review and interview with the Testing Personnel, the laboratory failed to establish written policies and procedures to include specimen collection, labeling, storage and preservation, acceptability and rejection, and specimen referral for 5 (October 2023 to February 2024) of 5 months since the laboratory started testing. Findings include: 1. An interview on 2/6/24 at 9:31 am with the Testing Personnel revealed the laboratory started patient testing in October 2023. 2. The surveyor observed a total of 14 patient urine specimens in the refrigerator on 2/6/24 at 9:58 am. Four specimens included only a first and last name on the specimen cup. 3. A review of the laboratories policies and procedures revealed a lack of specimen

	collection, labeling, storage and preservation, acceptability and rejection, and specimen referral policies and procedures. 4. An interview on 2/6/24 at 9:50 am with the Testing Personnel confirmed the laboratory had not established policies and procedures to include specimen collection, labeling, storage and preservation, acceptability and rejection, and specimen referral policies and procedures.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to establish written test procedures for 11 of 11 urine toxicology analytes on the laboratory's test menu. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of test procedures for the following urine toxicology analytes listed on the laboratory's test menu: a. Amphetamine b. Barbiturate c. Benzodiazipine d. Cocaine e. Creatinine f. Methadone g. Opiates h. Oxycodone i. Tetrahydrocannabinol (THC) j. Heroin k. Buprenorphine 2. An interview on 2/6/24 at 9:50 am with the Testing Personnel confirmed the laboratory had not established test procedures for the analytes listed above were not established.
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: . Based on observation and interview with the Testing Personnel, the laboratory failed to ensure quality control materials and wash solution were not used when expiration dates were exceeded for 18 total quality control materials and wash solution bottles observed. Findings include: 1. The surveyor observed the following quality control materials and wash solution that had exceeded expiration dates on 2/6/24 at 9:09 am: a. Washing Solution 4.5% Lot Number W162 expired 1/31/24, two bottles. b. MAS DOA Total Liquid Assay Drugs of Abuse Controls i. Levels 2, 3, 4, and 5 with "1/25/24" written on the bottles for the date opened and put into use had the expiration date of 12/31/2022, four bottles. ii. Level 2 Lot Number DAT22122A had the expiration date of 12/31/22, three bottles. iii. Level 3 Lot Number DAT22123A had the expiration date of 12/31/22, three bottles. iv. Level 4 Lot Number DAT22124A had the expiration date of 12/31/22, three bottles. v. Level 5 Lot Number DAT22125A had the expiration date of 12/31/22, three bottles. 2. An interview on 2/6/24 at 9:30 am with the Testing Personnel confirmed the quality control materials in use had exceeded expiration dates and the above supplies exceeded expiration dates.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 Testing Personnel, the laboratory failed to verify acceptability criteria for its urine toxicology control materials for 1 lot of controls observed. Findings include: 1. The surveyor observed the laboratory's control materials during a tour on 2/6/24 at 9:09 am: a. MAS DOA Total Liquid Assay Drugs of Abuse Controls i. Levels 2 (lot DAT22122A), 3 (lot DAT22123A), 4 (lot DAT22124A), and 5 (lot DAT22125A) with "1/25/24" written on the bottles for the date opened and put into use. 2. An interview on 2/6/24 at 10:28 am with the Testing Personnel indicated the laboratory was having issues getting controls within range. 3. The surveyor requested the laboratory's verification of control materials on 2 /6/24 at 11:21 am and it was not made available. 4. An interview on 2/6/24 at 11:21 am with the Testing Personnel confirmed the laboratory did not verify the criteria for control material acceptability for its urine toxicology control materials.
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 Testing Personnel, the laboratory failed to perform corrective action for patients receiving urine toxicology testing when quality control testing was out of range for 4 (11/24/23, 12/2/23, 12/15/23, 12/22/23, and 1/3/24) of 5 testing dates reviewed. Findings include: 1. A review of the laboratory's "Daily QC" policy revealed a section stating, "If a QC fails, the test will appear on the left side of F1 Home screen and be highlighted in yellow. Click on the test to review" and lacked specified ranges. 2. The surveyor requested the manufacturer ranges for the controls on 2/6/24 at 10:28 am and they were not made available. 3. A review of the laboratory's quality control records on patient testing dates revealed a column indicating when controls had violated a rule. All control results with a number in the violation column had a z-score that was at least +/- 2.00.

	The following control results had a rule violation and a z-score of +/- 2.00 or greater: a. 11/24/23 i. Amphetamine high control had a z-score of 3.06. ii. 6-AM high control had a z-score of -2.25. iii. Buprenorphine high control had a z-score of -2.00. iv. Creatinine high control had a z-score of -11.24. v. Oxycodone level 4 control had a z-score of 2.58. vi. Creatinine low control had a z-score of -4.00. vii. Barbiturates level 4 control had a z score of 2.44. b. 12/2/23 i. Opiates level 2 control had a z-score of 2.06. ii. Cocaine level 4 control had a z-score of 2.04. iii. Amphetamines level 4 control had a z-score of 3.32. iv. 6-AM high control had a z-score of -2.04. v. Buprenorphine high control had a z-score of -2.17. vi. Oxycodone level 4 control had a z-score of 2.77. vii. Methadone level 2 control had a z-score of 2.0. viii. Barbiturates level 4 control had a z-score of 2.92. c. 12/15/23 i. Tetrahydrocannabinol (THC) level 4 control had a z-score of 3.17. ii. Opiates level 2 control had a z-score of 3.21. iii. Amphetamines level 5 had a z-score of 5.23 and level 4 had a z-score of 5.23. iv. Cocaine level 4 had a z-score of 4.29. v. 6-AM high control had a z-score of -2.42. vi. Buprenorphine high control had a z-score of 3.58 and the low control had a z-score of 3.89. vii. Oxycodone level 4 had a z-score of 3.94. viii. Methadone level 2 had a z-score of 3.33. ix. Benzodiazepine level 4 had a z-score of 2.08. x. Barbiturates level 4 had a z-score of 5.33 and level 5 had a z-score of 2.47. d. 12/22/23 the analyte 6-AM high control had a z-score of -2.04. e. 1/3/24 i. Creatinine high control had a z-score of 4.00. ii. Creatinine low control had a z-score of 3.14. 4. The surveyor requested corrective action performed for the failed control values listed above on 2/6/24 at 10:28 am and it was not available. 5. An interview on 2/6/24 at 10:28 am with the Testing Personnel confirmed the laboratory did not perform corrective action for patients that had testing reported when controls were out of range.
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 Testing Personnel, the laboratory failed to include a second patient identifier, units of measurement, and reference ranges used for interpretation on the test report for 4 (Patients 1-4) of 4 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed the laboratory failed to include a second patient identifier, units of measurement, and reference ranges used for interpretation for the following patient test reports: a. Patient 1 reported on 2/2/24. b. Patient 2 reported on 12/22/23. c. Patient 3 reported on 1/3/24. d. Patient 4 reported on 11/24/23. 2. An interview on 2/6/24 at 10:37 am with the Testing Personnel confirmed the laboratory did not include a second patient identifier, units of measurement, and reference ranges used for interpretation on test reports.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the Laboratory Director failed to ensure a quality control program was established to include verification of control materials (refer to D6020), failed to ensure quality assessment programs were established (refer to D6021), failed to ensure patient test results were reported only when control procedures had been within acceptable range (refer to D6025), failed to ensure test reports included a second patient identifier, units of measurement, and reference ranges used for interpretation on the test report (refer to D6026), failed to employ personnel to serve as Technical Consultant (refer to D6028 A), failed to ensure testing personnel were qualified prior to performing moderately complex testing (refer to D6028 B), failed to ensure competency assessment policies and procedures to assess Clinical Consultant, Technical Consultant, and Testing Personnel competency were established (refer to D6030), failed to ensure written policies and procedures for specimen collection, labeling, storage and preservation, acceptability and rejection, and specimen referral were established (refer to D6031 A), and failed to ensure written test procedures for 11 of 11 urine toxicology analytes were established (refer to D6031 B).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure a quality control program was established to include verification of control materials. Refer to D5469.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure quality assessment programs were established for 5 (October

	2023 to February 2024) of 5 months since the laboratory initiated patient testing. Findings include: 1. An interview on 2/6/24 at 9:31 am with the Testing Personnel revealed the laboratory started moderate complexity patient testing in October 2023. 2. The surveyor requested the laboratory's quality assessment program and documentation on 2/6/24 at 9:45 am and it was not made available. 3. An interview on 2/6/24 at 9:50 am with the Testing Personnel confirmed a quality assessment program had not been established.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) 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 with the Testing Personnel, the Laboratory Director failed to ensure patient test results were reported only when control procedures had been within acceptable range. Refer to D5783.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure test reports included a second patient identifier, units of measurement, and reference ranges used for interpretation on the test report. Refer to D5805.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

	This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to employ personnel to serve as Technical Consultant. Refer to D6034. B. Based on record review and a lack of documentation, the Laboratory Director failed to ensure testing personnel were qualified prior to performing moderately complex testing. Refer to D6065.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to ensure competency assessment policies and procedures to assess Clinical Consultant, Technical Consultant, and Testing Personnel competency were established. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure written policies and procedures for specimen collection, labeling, storage and preservation, acceptability and rejection, and specimen referral were established. Refer to D5311. B. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure written test procedures for 11 of 11 urine toxicology analytes were established. Refer to D5401.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

	accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to employ personnel to serve as Technical Consultant (refer D6034).
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to employ personnel to serve as Technical Consultant for 5 (October 2023 to February 2024) of 5 months since the laboratory initiated testing. Findings include: 1. An interview on 2/6/24 at 9:31 am with the Testing Personnel revealed the laboratory started moderate complexity patient testing in October 2023. 2. The surveyor requested the qualifications and information for personnel serving as the Technical Consultant on 2/6/24 at 9:37 am and it was not made available. 3. An interview on 2/6 /24 at 9:37 am with the Testing Personnel confirmed the laboratory did not employ personnel to serve as Technical Consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel were qualified prior to performing moderately complex testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at

	least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel were qualified prior to performing moderately complex testing for 1 (Testing Personnel #1) of 1 testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel records revealed a lack of documentation of qualifications for Testing Personnel #1 to meet the requirements at 493.1423. 2. The surveyor requested additional qualification documentation for Testing Personnel #1 on 2/6/24 at 9:37 am and they were not made available. 3. The laboratory was provided and additional 7 days to provide the missing qualification documents and they were not made available.