Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2053614	09/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Synergy Medical Laboratories Inc	152 State Route 35, Keyport, NJ	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Proficency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate results when they received Not Graded score in Chemistry - Core with American Proficiency Institute in the 1st and 2nd events of 2019. The findings include: 1. There was no evaluation documented when the laboratory received "Not Graded" for analytes Alkaline Phosphatase sample CH-01, Alanine Aminotransferease sample CH-04, Gamma-glutamyltransferase samples CH-02 through CH-05 for 1st event 2019. 2. There was no evaluation documented when the laboratory received "Not Graded" for analytes Albumin Sample CH-06, Alkaline Phosphatase Samples CH-06 through CH-10, Alanine Aminotransferease sample CH-06, Chloride sample CH-08, Creatine Kinase sample CH-09, Potassium sample CH-08, Sodium sample CH-08, Thyroid Stimulating Hormone sample CH-07 for 2nd event 2019. 3. There was no documented evidence the laboratory evaluated coded results. 4. The TS confirmed on 9/18/19 at 11: 00 am that the laboratory did not perform and document an evaluation of unacceptable PT results. 35471 b) Based on surveyor review of the PT records and interview with the TS, the laboratory failed to evaluate flagged and Unacceptable (U) results obtained with Pennsylvania Department of Health PT for Drugs of Abuse in Urine in the calendar year 2018. The findings include: 1. There was no evaluation documented when the laboratory received a "flag" on the Methadone result in the 1st event of 2018. 2. There was no evaluation documented when the laboratory received a U in the 3rd event of 2018. 3. There was no evidence the laboratory evaluated the failures. 4. The TS confirmed on 9/18/19 at 10:00 am that the laboratory did not perform and document an evaluation of unacceptable PT results.

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 surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to have all procedures needed for Urine Toxicology tests run on the Applied Biosystem Sciex Triple Quad 6500 from March 2019 to the date of the survey. The findings include: 1. The laboratory failed to have procedures for: a. Verification of new lots of reagents, prepared mobile phases and standards before they were put in use. b. Acceptance criteria for results with an "Ion Ratio Failure". c. Corrective action to be taken when controls fail or system becomes inoperable. 2. The TS confirmed on 9/18/19 at 1:50 pm that the laboratory did not have the above procedures.
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 surveyor observation of the Quality Control (QC) material in use and interview with the Technical Supervisor (TS) the laboratory failed to label the control material used in Hematology testing with an open and new expiration date after opening at the time of survey. The findings include: 1) There was no open and expiration date written on the QC material. 2) The TS confirmed on 9/18/19 at 10:10 am controls were not labeled.
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 surveyor observation of Quality Control (QC) material in use, review of the Bio-Rad Liquichek Urine Toxicology control kit Manufacture's Package Insert (MPI) and interview with the Technical Supervisor (TS), the laboratory used expired QC material for the Toxicology testing performed on the Beckman Coulter AU480 analyzer from 8/16/19 to the date of survey. The findings include: 1. The MPI stated open vial stability was for 30 days. 2. The laboratory did not know control material expired 30 days after opening. 3. The open date on the QC material was 7/16/19. 4. The expiration date written on the QC material was 12/16/19 5. 200 patients were run and reported with expired QC. 6. The TS confirmed on 9/18/19 at 11:00 am that the laboratory used expired QC material. b) Based on surveyor observation of Quality Control (QC) material in use, review of the Bio-Rad Liquichek Urinalysis control kit Manufacture's Package Insert (MPI) and interview with the Technical Supervisor (TS), the laboratory used expired QC material for urine creatine testing performed on the Beckman Coulter AU480 analyzer from 6/15/2019 to the date of survey. The findings include: 1. The MPI stated open vial stability was for 30 days. 2. The laboratory did not know control material expired 30 days after opening. 3. The open date on the QC material was 5/15/19. 4. 3000 patients were run and reported with expired QC. 5. The TS confirmed on 9/18/19 at 11:00 am that the laboratory used expired QC material.
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 surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that PS were performed for Routine Chemistry tests on the Beckman Coulter (BC) AU480 from November 2017 to the date of survey. The findings include: 1. The laboratory did not perform accuracy or a range study on all analytes performed on the AU480 . 2. The laboratory did not perform precision and linearity on Sodium, Potassium, and Chloride performed on the AU480. 3. The TP confirmed on 9/18/19 at 10:30 am that PS were not performed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specifications (PS) and interview with the Technical Supervisor (TS), the laboratory failed to have complete PS for Urine Drug tests performed on the AbSciex Triple Quad 6500 from March 2019 to the day of the survey. The findings include: 1. A review of the PS revealed the laboratory did not establish performance characteristics as follows: a. The validation of the hydrolysis control did not include validation of: i. Optimal Enzyme Concentration ii. Temperature of the Heat Block iii. Time on the Heat Block b. The laboratory failed to have acceptable criteria for PS from clinical scientific literature. c. There was no source available for cut off points. d. There was no criteria to review chromatography. e. There was no criteria for manual integration of peaks. f. Method comparison studies were not performed. g. Acceptable criteria for precision and accuracy were not established. 2. The TS confirmed on 9/18/19 at 2:20 pm that the LD did not ensure that all PS were established.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Technical Supervisor (TS), the laboratory failed to prepare control and calibrator material from different lot numbers of standards for Urine Toxicology confirmation tests from 3/30/17 to the date of the survey. The TS stated on 9/18/19 at 2:10 pm the laboratory did not use different lot numbers to prepare calibrators and controls.
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 surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for tests performed on the Beckman Coulter AU 480, Beckman Coulter Adiva Centuar, and Hematology analyzers from June 2018 to the date of survey. The TS confirmed on 9 /18/19 at 1:00 pm that the laboratory did not verify QC materials.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to identify problems on the FR for urine Drug Confirmation tests performed on the AB Sciex Triple Quad 6500 from 3/30/17 to the date of the survey. The findings include: 1. The Cutoff value for Methadone on the FR is 50 ng/ml but a review of the Performance Specifications revealed it to be 100 ng /ml. 2. The Cutoff value for Methlyphenidate on the FR is 50 ng/ml but a review of linearity revealed the Lower Limit Of Quantification (LLOQ) is 100 ng/ml. 2. The TS confirmed on 9/18/19 at 1:30 pm the the laboratory did not identify problems on the FR.
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 surveyor review of the PS records and interview with the TS, the LD failed to ensure that PS were adequate to perform Endocrinology tests on the BC Advia Centaur and Siemans Ca-600 series Coagulation analyzer from November 2017 to the date of survey. The findings include: 1. There was no evidence of LD review. 2. There was no criteria established for accuracy, Precision and linearity. 3. The TS confirmed on 9/18/19 at 11:30 am that PS were not adequate.