Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D2053614	**(X3) Date Survey Completed** 03/31/2021
Name of Provider or Supplier Synergy Medical Laboratories Inc	**Street Address, City, State** 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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the review of Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to enroll in an approved PT program for Prothrombin Time and International Normalized Ratio (PTT/INR) test from November 2019 to the date of survey. The GS confirmed on 3/31/21 at 1:00 pm the laboratory was not enrolled in PT testing for PTT/INR.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test

	system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to maintain the Work Records (WR) and Attestation Statements (AS) signed by the laboratory director for Chemistry and Hematology tests performed with the American Proficiency Institute (API) in 2019 and 2020. The findings include: 1. The laboratory did not document handling, processing and each step in the testing and reporting of PT samples. 2 . There were no PT WR available for the Beckman Coulter AU 480 for 2019 and 2020. 3 . There was no AS for 2019 Chemistry - Core- 2nd and 3rd Event 4 . The TS confirmed on 3/31 /21 at 2:15 pm that the laboratory did not maintain complete records for PT.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), it was revealed that the laboratory failed to review "not graded" results obtained for Chemistry PT performed with the American Proficiency Institute (API) in 2019. The finding includes: 1.Ungraded results were received for: 2019 Chemistry- Core- 1st Event: Alanine Transaminase- Sample CH-04, Gamma-Glutamyl Transferase- Samples CH-02 through CH-05 2. The TS confirmed on 03/31 /21 at 2:30 pm that the laboratory failed to evaluate "not graded" PT results.
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: Based on surveyor review of Proficiency Testing (PT) results and interview with the Technical Supervisor (TS), the laboratory failed to evaluate results when the laboratory received unacceptable scores for Chemistry and Hematology Testing performed with the American Proficiency Institute (API) in 2019 and 2020. The findings include: 1. The laboratory received unacceptable grades in the following events: a. 2019 Chemistry- Core- 1st Event : Albumin- Sample CH-02, LDL Cholesterol -Sample CH-02, Phosphorus- Samples CH-02 and CH-03 b. 2019 Chemistry- Core- 2nd Event : Albumin- Sample CH-06, Alkaline Phosphatase- Samples CH-06 through CH-10, ALT/SGPT- 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 c. 2019 Chemistry- Core- 3rd Event : ALT/ SGPT- Samples CH-11 and CH-12, Calcium Total - Samples CH-12 through CH-15, Creatinine- Samples CH-12 through CH-15, Iron, Total- Samples CH-11 and CH-12, Phosphorus- Samples CH-12 through CH-15, Urea Nitrogen/ BUN- Sample CH-14, Thyroxine- Sample CH-15 d. 2020 Chemistry- Core - 1st Event :

	Chloride- Sample CH-04, Iron/ Total- Sample CH-04,Phosphorus- Sample CH-01, Urea Nitrogen/ BUN- Sample CH-05 e. 2020 Chemistry - Core- 2nd Event : ALT/ SGPT- Sample CH-09, Glucose- Sample CH-09, Phosphorus- Samples Ch-07 and CH-10, TIBC, measured- Samples CH-06 through CH-10 f. 2019 Hematology/ Coagulation - 1st Event: Basophils- Sample PNT-03 g. 2020 Hematology/ Coagulation- 1st Event: Monocytes- Sample PNT-05 2. No evaluation or corrective action was documented for the unacceptable PT scores. 3. The TS confirmed on 3/31 /21 at 2:55 pm that the laboratory did not perform and document an evaluation of unacceptable PT results. * Note- this is a repeat citation (previously cited on survey from 9/8/19)
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: a) Based on the lack of the Procedure Manual (PM), Sysmex CA-620, and Advia Centaur Xp operators manual and interview with the Testing Personnel (TP), the laboratory failed to have written procedures for Endocrinology, Immunology and Coagulation tests performed by the laboratory from 9/18/19 to the date of survey. The TP #2 listed on CMS form 209 confirmed on 3/30/21 at 11:00 am that the laboratory did not have written procedures for all tests performed by the laboratory. b) Based on surveyor review of the PM, and interview with the TP, the laboratory failed to follow the "Establishment of Control Ranges for AU480" procedure for Routine Chemistry tests from 9/18/19 to the date of survey. The findings include: 1. The PM stated to "Assay new control material a minimum 10 times" but Bio-Rad liquid assayed Multiqual controls were assayed seven times. 2. The TP #2 listed on CMS form 209 confirmed on 3/30/21 at 1:00 pm that the laboratory did not follow the "Establishment of Control Ranges for AU480" procedure.
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 Testing Personnel (TP), the laboratory failed to include an accurate procedure for Critical Values (CV) obtained on the Beckman Coulter AcT5 analyzer used for Hematology testing from September 2019 to the date of the survey. The findings include: 1. The laboratory had a CV procedure but they did not define what constitutes a critical value. 2. The TP #1 listed on CMS form 209 confirmed on 3/31 /21 at 2:20 pm that an accurate CV procedure was not established.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturers Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to follow the MPI for Coagulation testing performed on the Sysmex CA-620 analyzer from 9/18/19 until the date of survey. The findings include: 1. The Dade Innovin MPI stated to establish a Normal Patient Mean (NPM) with each new lot of reagent but the laboratory did not establish a NPM with the lots used from 9/18/19 to the date of survey. 2. Approximately 110 patients were run and reported. 3. The GS confirmed on 3/31/21 at 11:00 am that the MPI was not followed.
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 Procedure Manual (PM) and interview with theTesting Personel (TP), the laboratory failed to document the Reportable Range (RR)/Linearity established by the manufacturer for Hematology Tests performed on the Beckman Coulter AcT5 from 9/18/19 to the date of survey. The finding includes: 1. The laboratory had no documentation in the PM or in the room with the Beckman Coulter AcT5 Diff analyzer which indicated the linearity or RR of Hematology parameters. 2. The TP #1 listed on CMS form 209 confirmed on 3/31/21 at 12:50 pm that the laboratory did not have RR/Linearity documentation.

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 lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least once every six months for Immunology and Endocrinology Tests performed on the Advia Centaur Xp and Hematology Testing on the Beckman Coulter AcT diff 5 analyzer from 9/18/19 to the date of the surveyor. The TP #3 listed on the CMS form 209 confirmed on 3/31/21 at 12:10 pm CV was not performed every six months.
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 General Supervisor (GS), the laboratory failed to prepare control and calibrator material from different lot numbers of standards for Urine Toxicology confirmation tests from 9/18/19 to the date of the survey. The GS confirmed 3/31/21 at 1:40 pm that the laboratory did not use different lot numbers to prepare calibrators and controls. Note: This was cited on the previous survey performed on 9/18/19
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 the lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Siemens control material performed on the AU680 and Sysmex CA-620 and from 9/8/19 until the date of survey. The TP #2 listed on the CMS form 209 confirmed on 3/30/21 at 10:15 am that the assayed values of QC material were not verified before putting in use.
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 surveyor review of the Quality Control (QC) records and interview with Testing personnel (TP), the laboratory failed to take corrective action when one out of two levels of controls were out of range for Vitamin B12, Folate, Vitamin D, and Luteinizing Hormone (LH) tests performed on Advia Centaur Xp analyzer from 12/16/20 to the date of survey. The findings include: 1. Biorad Lyphocheck Immunoassay Plus Control level 1 Lot number 40391 was out of range as below: a. 1/4/21 and 12/30/20 for Vitamin D b. 12/14/20 and 12/16/20 for Vitamin B12 c. 12/28/20 and 2/26/21 for Folate d. 1/8/21 for LH 2. There was no corrective action documented for the above failures. 3. Approximately thirty patient samples were run and reported. 4. The TP #3 list on CMS form 209 confirmed on 3/31/21 at 11:00 am that no corrective action was taken for out of range QC.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP) the laboratory failed to have a procedure to verify new lots of controls before they were put in use for tests performed on the Beckman AU680, Advia Centaur XP, and Sysmex Ca-620 from 9/18/19 to the date of the survey. The TP #2 listed on CMS from 209 confirmed on 3/31/21 at 11:30 am that laboratory did not have the above procedures. b) Based on surveyor review of the Quality Control (QC) material, QC data onboard the analyzer and interview with TP, the laboratory failed to assess and correct problems in the analytic system when the onboard QC had the incorrect control lot number and expiration dates for Coagulation tests run on the Sysmex CA-620 from 9/20/19 to the date of survey. The findings include: 1. The onboard Level 1 and 3 C-Trol QC lot numbers and expiration dates did not match the current QC material in use. a) Onboard Level 1 C-Trol Lot number 548049 expiration 9/20/19 but in use Level 1 C-Trol Lot 548097 expiration date 2/24/22. b) Onboard Level 3 C-Trol Lot 548483 expiration 9/20/19 but in use level 3 C-Trol lot 556517 expiration 1/29/22. 2 The TP#2 listed on CMS from 209 confirmed on 3/31/21 at 11: 45 am that the laboratory did not assess and correct problem in the analytic system.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Chemistry and Hematology testing performed with American Proficiency institute (API) in the calendar year 2019 and 2020. The TS confirmed on 3/31/21 at 2:15 pm that the PT results were not reviewed.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by:

	Based on surveyor review of the Coagulation Records and interview with the Testing Personnel (TP) the General Supervisor (GS) failed to ensure the establishment and maintenance of acceptable levels of analytical performance for coagulation tests performed on the Sysmex CA-620 from 9/18/19 until date of survey. The findings include: 1) A calculation check on patient work records using an ISI of 1.04 and a NPM of 10.9 revealed that twelve out of twelve INR test results were calculated incorrectly. 2) The GS could not determine when the last patient mean was calculated. 3) The GS confirmed on 3/31/21 at 1:00 pm the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for coagulation tests.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Sysmex CA-620 analyzer on the date of survey. The TP#2 on CMS form 209 confirmed on 3/31/21 at 12:45 pm that trends and shifts were not reviewed.
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 an surveyors review of the laboratory's records, procedures and interview with the Testing Personnel (TP) and the General Supervisor (GS), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 9/18/19 to the date of the survey. 1. The LD failed to enroll in an approved PT program for Prothrombin Time and International Normalized Ratio (PTT/INR) Cross refer to D 2000. 2. The LD failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action. Cross refer D 6018. 3. The LD to ensure the establishment and maintenance of acceptable levels of analytical performance for coagulation tests. Cross refer D 6023. 4. The LD failed to ensure a Quality Assurance (QA) program was established. Cross refer D 6094. 5. The LD failed to ensure that the education records were available. Cross refer D6102
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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: Based on surveyor review of the lack of laboratory procedures and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from 9/18/19 to the date of the survey. The TP #2 listed on CMS from 209 confirmed on 3/31/21 at 10:25 am the LD did not establish a QA program.
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: Based on surveyor review of Personnel Records (PR) and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that the education records were available on the date of the survey. The finding includes: 1. Education records were not available for two of three Testing Personnel (TP). 2. The TS confirmed on 03/31/2021 at 1:00 pm that education records were not available.