Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2053614	10/22/2025
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: A) Based on surveyor review of the Test Records (TR), Quality Control (QC) and interview with the General Supervisor (GS), the laboratory failed to retain documentation of all analytical system activities records for two years for Chemistry testing performed on the Beckman Coulter AU480 from 3/31/21 to 10/9/25. The findings includes. 1. The hard drive for the Beckman Coulter AU480 crashed on 10/9 /25. 2. The data on the hard drive was not backed up and was lost. 3. The GS confirmed on 10/22/25 at 12:45 PM the laboratory did not retain all analytical system activities records. B) Based on surveyor review of the Quality Control Records (QCR) and interview with the General Supervisor (GS), the laboratory failed to document all Quality Control (QC) information for Chemistry tests performed on the Beckman Coulter AU480 analyzer from to 3/31/21 to 10/22/25 . The finding includes: 1. The laboratory did not document the lot numbers and expiration dates of QC material used on QCR for the Beckman Coulter AU480 analyzer. 2. The GS confirmed on 10/22/25 at 1:30 pm, the laboratory did not document all QC information.
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 General Supervisor (GS), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Chemistry in the calendar year 2025 . The findings include: 1. The laboratory did not evaluate "Not Graded 1", "See Data Summary" responses from API in event 1, 2025 for the following: a) Bilirubin, Direct (mg/dL) samples CH-01,02,03,04,and 05. 2. The laboratory did not evaluate "Not Graded 1", "See Data Summary" responses from API in event 3, 2025 for the following: a) Bilirubin, Direct (mg/dL) samples CH-11,13,13,14 and 15 3. The GS confirmed on at 10:30 am on 10/21/25 that the laboratory failed to evaluate the above mentioned coded results.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS) laboratory failed to verify the accuracy and received a score that did not reflect the performance of Total Bilirubin test results obtained from the American Proficiency Institute (API) for the Chemistry-Core 3rd event 2025. The findings include: 1. The laboratory received a score of 100% but received a "Not Graded 1" for Total Bilirubin samples CH-12 and CH-15. 2. API reported the range for Total Bilirubin sample CH-12 as 1.4 - 2.3 mg/dL. 3. The laboratory reported Sample CH-12 as out of range for Total Bilirubin with 2.5 mg/dL. 4. API reported the range for Total Bilirubin sample CH-15 as 1.0 - 1.9 mg/dL. 5. The laboratory reported Sample CH-15 as out of range for Total Bilirubin with 2.0 mg/dL. 6. After evaluation of the "Not Graded 1" results the laboratory obtained a score of 60% 7. The GS confirmed on 10/21/25 at 10:20 am the laboratory received a PT score that did not reflect the laboratories performance of Total Bilirubin testing.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 surveyor review of the Procedure Manual (PM), Quality Control (QC) and interview with the General Supervisor (GS) the laboratory failed to follow the laboratories procedure "Establishment of Control Ranges" for the Advia Centaur XP analyzer used to perform Endocrinology and Virology testing from 3/31/21 to 10/21 /25. The findings include: 1. The procedure "Establishment of Control Ranges" stated

	"4. Compare received values (i.e. mean and SD) for new control to the manufacturer's published value sheet for the respective analyzer or method utilized. Recovered values must be within +/- 10% for the manufacturer's published range depending on the assay being evaluated (e.g. some enzyme assays may vary by +/- 30%)" 2. There was no documented evidence that the above mentioned procedure was performed prior to putting new QC lots into use. 3. The GS confirmed on 10/21/25 at 10:55 am, the laboratory failed to follow the above menrioned prcoudre.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 Quality Control (QC), review of the Liquichek Assayed Multiqual manufactuers Assay Value Sheet (AVS) and interview with the General Supervisor (GS), the laboratory failed to follow the AVS for the Routine Chemistry testing performed on the Beckman Coulter AU480 analyzer from 3/31/21 to 10/22/25. The findings include: 1. The laboratory used QC values outside the manufactuersAVS range for the following analytes. a. Amylase b. High-density lipoprotein c. Phosphate d. Uric Acid e. Calcium 2. The GS confirmed on 10/22/25 at 2:00 pm that the laboratory failed to follow the manufactuers AVS.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 the lack of Calibration Verification (CV) records and interview with the General Supervisor (GS), the laboratory failed to perform and document CV procedures at least every six months on the Adiva Centaur XP analyzer from 3/31/21 to 10/22/25. The findings include; 1) The laboratory is running two levels of Quality

	Control (QC) on the Adiva Centaur XP analyzer for Endocrinology, Virology and Chemistry testing. 2) There was no documented evidence that a linearity was performed every six months. 3) The GS confirmed on 10/22/25 at 1:30 pm that a linearity was not performed every six months on the Adiva Centaur XP analyzer.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 General Supervisor (GS), the laboratory failed to take corrective action when two out of three levels of controls were out of range tests performed on the Adiva Centaur XP analyzer from 10/9/25 to 10/22/25 the date of survey. The findings include: 1. Control levels were out as follows: a. Liquid Assayed Multiqual level 2 and 3 Lot number 46030 for Calcium was out of range 10/13/25. b. Liquid Assayed Multiqual level 1 and 2 Lot number 46030 for High-density lipoprotein was out of range 10/9/25 and 10 /10/25. c. Liquid Assayed Multiqual level 1 and 2 Lot number 46030 for Uric Acid (URIC) was out of range 10/9/25 and 10/10/25, 10/14/25, 10/15/25, 10/26/25, 10/17 /25, 10/20/25. d. Liquid Assayed Multiqual level 1, 2 and 3 Lot number 46030 for URIC was out of range 10/13/25. e. Liquid Assayed Multiqual level 2 and 3 Lot number 46030 for Amylase was out of range 10/14/25. f. Liquid Assayed Multiqual level 1 and 3 Lot number 46030 for Creatine Kinase (CK) was out of range 10/10/25, 10/14/25, 10/15/25, 10/16/25, 10/20/25, 10/21/25 g. Liquid Assayed Multiqual level 1, 2 and 3 Lot number 46030 for CK was out of range 10/9/25. h. Liquid Assayed Multiqual level 1 and 2 Lot number 46030 for Phosphate (PHOS) was out of range 10 /9/25. i. Liquid Assayed Multiqual level 1, 2 and 3 Lot number 46030 for PHOS was out of range 10/14/25, 10/15/25, 10/16/25, 10/17/25, 10/20/25. j. Liquid Assayed Multiqual level 2 and 3 Lot number 46030 for PHOS was out of range 10/21/25 2. There was no corrective action documented for the above failures. 3. Approximately 25 patient samples were run and reported daily. 4. The GS confirmed on 10/22/25 at 1: 00 pm that no corrective action was taken for out of range QC.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to establish a procedure for periodically verifying the accuracy of calculated data by the Lab Information System (LIS) from 4/1/23 to 10/22/25. The finding includes. 1. The laboratory did not have a

	procedure for verifying Estimated Glomular Filtration Rate (eGFR) calculations by the LIS. 2. The GS confirmed on 10/22/25 at 1:30 pm, the laboratory did not verify the accuracy of calculated data by the LIS.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 Quality Control (QC) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to maintain a QC program to assure the quality of laboratory service from 3/31/21 to 10/21/25. The finding includes: 1. There was no evidence of review of shifts and/or trends for testing performed on the Adiva Centaur XP. 2. The GS confirmed on 10/21/15 at 2:45 PM, the QC program was not maintained.