Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2145552	07/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Simplicity Health	3260 42nd Ave S, Saint Cloud, MN	

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
D0000	. A complaint investigation was completed on July 18, 2025. Immediate Jeopardy existed for the following condition level deficiencies: D5400 493.1250 Condition: Analytic Systems D6000 493.1403 Condition: Laboratory Director .
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, document review, and interview with laboratory personnel, the laboratory failed to follow safety procedures for the disposal of biohazardous materials 2025. Findings are as follows: 1. The laboratory performed venipuncture to collect blood specimens for Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 7/16/25. 2. Two large, open sharps containers were observed on the floor of the blood-drawing room next to patient chairs. The lid of one sharps container was not secured and was two-thirds full of biohazardous venipuncture materials. 3. Biohazard materials were to be "stored safely and securely" to prevent exposure and contamination as defined in the Quality Assurance Plan at Simplicity Health policy found in the Project Quality Assurance Plan binder provided by the laboratory on the date of survey. 4. In an interview at 11: 21 a.m. on 7/16/25, TP3 confirmed the above findings. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

	procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on review of laboratory policies and procedures, patient testing and quality control logs, direct observation, and interview with laboratory personnel, the laboratory failed to meet the analytic systems requirements for chemistry. Findings are as follows: 1. The laboratory failed to follow verbal manufacturer instructions for one of three chemistry analyzers prior to reporting two patient test results in February 2025. See D5411 2. The laboratory failed to complete all required performance verification (PV) activities for 24 of 24 analytes on a new chemistry analyzer prior to reporting patient test results in 2025. See D5421 3. The laboratory failed to ensure two levels of quality control material (QC) were performed and acceptable on one of three chemistry analyzers on 13 of 66 days of testing in April, May, and June 2025. See D5447 .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to follow verbal manufacturer instructions for one of two chemistry analyzers in use prior to reporting two patient test results in February 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 07/16/25. 2. A Tosoh AIA-2000 analyzer was observed as present and available for use during the tour. The laboratory performed Vitamin D testing using this analyzer. 3. Review of the laboratory's Tosoh AIA-2000 corrective action logs found in the Corrective Action Logs manual revealed the laboratory was unable to perform Vitamin D quality control testing on the Tosoh AIA-2000 chemistry analyzer on 02/05/25 due to error message "pretreat 2 shortage error". 4. The laboratory contacted the manufacturer on 02/05/25 and was verbally instructed to discontinue Vitamin D testing on the analyzer until service was scheduled to be completed on 02/10/25 as indicated on the Tosoh AIA-2000 2/5/25 Corrective action document. 5. The laboratory performed and reported Vitamin D results on two patient samples on 02/07/25 as indicated on the Tosoh AIA-2000 Patient Report obtained from the analyzer and provided by the laboratory on 07/17/25. 6. In an interview at 12:18 p.m. on 07/17/25, TP3 confirmed the above finding. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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, document review, and interview with laboratory personnel, the laboratory failed to ensure specimen collection materials were not used after the expiration had been exceeded, potentially affecting 56 of 56 patient test results obtained in 2025. Findings are as follow: 1. The laboratory supplied Endocervical and Male Urethral swab specimen collection kits to patient exam rooms for Microbiology testing performed at the reference laboratory as confirmed by TP3 during a tour of the laboratory at 8:14 a.m. on 7/16/25. 2. One expired Aptima Unisex Swab Specimen Collection Kit was observed as present and available for use in the laboratory during the tour. Ten expired Aptima Unisex Swab Specimen Collection Kits were observed in 6 of 15 patient exam rooms on 7/16/25. See below. Location # of Swabs Lot# Expiration Laboratory One 904401V 6/30/25 Exam 7 One 904401V 6/30/25 Exam 8 One 904401V 6/30/25 Exam 11 One 904401V 6/30/25 Exam 24 Two 898938V 3/31 /25 Exam 25 One 904401V 6/30/25 Exam 27 One 898938V 3/31/25 Exam 27 Three 904401V 6/30/25 3. In an interview at 12:23 p.m. on 7/16/25, TP3 confirmed the above findings. 4. The laboratory sent 56 Aptima Endocervical swabs to the reference lab since 1/31/25, as indicated by TP3 in an interview at 11:04 a.m. on 7/17/25. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 observation, document review, and interview with laboratory personnel, the laboratory failed to complete all required performance verification (PV) activities for 24 of 24 analytes on a new chemistry analyzer prior to reporting patient test results in 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 07/16/25. 2. A Horiba Pentra 400 analyzer was observed as present and in use during the tour. The laboratory implemented testing using this analyzer as indicated below. 03/25/25 Basic Metabolic Panel Amylase Lipase Magnesium Uric Acid 04/16 /25 Comprehensive Metabolic Panel Liver Function Panel Renal Function Panel Lipid Panel 05/12/25 C-Reactive Protein (CRP) 3. PV documentation for the Horiba Pentra 400 chemistry analyzer included accuracy verification via method comparison data, precision data, and linearity data completed in October 2024 through March 2025. The following items were not found: -Accuracy data for 3 of 24 analytes; Magnesium, Phosphorus, Uric Acid -Linearity data (reportable range) for 6 of 24 analytes; Amylase, Lipase, Magnesium, Phosphorus, Uric Acid, C-Reactive Protein (CRP) - Reference range verification documentation for 24 of 24 analytes The laboratory was unable to provide the missing documentation upon request. 4. The following 399 patient test results were reported without accuracy and/or reportable range verification from date of implementation through 07/16/25: Amylase - 19 Lipase - 66 Magnesium

	- 86 Phosphorus - 16 Uric Acid - 83 CRP - 129 5. Review of procedures for each individual analyte, found in an untitled manual, revealed the laboratory adopted the manufacturer's analytical measuring range (AMR) as their reportable range for 24 of 24 analytes. Values obtained during the PV did not reach the upper and/or lower limits of the AMR for 18 of 24 analytes. See below. Analyte PV AMR Albumin 1.7-7.8 0.09-5.6 Alkaline Phosphatase 5-1154 10-1500 Amylase none 4.5-2000 Direct Bilirubin 0.41-34.83 0.16-33.90 Blood Urea Nitrogen 0.2-129.7 2.8-140.3 Calcium 1.3-16.0 4.0-18.0 Cholesterol 16-514 8-581 Cholesterol HDL 8-188 2.0-174.15 Chloride 61-196 70-200 Carbon Dioxide 3.0-42.2 1.8-60.8 Glucose 8-883 3-900 Lipase none 8-321 Magnesium none 0.32-4.62 Phosphorus none 0.3-24.1 Total Protein 2.6-11.9 0.7-16.0 Triglycerides 7-763 12-1137 Uric Acid none 0.3-25.0 CRP none 1-160 6. In an interview at 12:25 a.m. on 07/16/25, TP3 confirmed the above finding. 7. In an email received at 3:10 p.m. on 07/21/25, TP3 indicated 16,220 results were reported since test implementation to 07/17/25 for the following analytes with incorrect reportable ranges: Analyte Number of tests reported Albumin 999 Alkaline Phosphatase 1064 Amylase 20 Direct Bilirubin 72 Blood Urea Nitrogen 1802 Calcium 1808 Cholesterol 1149 Cholesterol HDL 1149 Chloride 1802 Carbon Dioxide 1802 Glucose 1961 Lipase 66 Magnesium 88 Phosphorus 16 Total Protein 1062 Triglycerides 1144 Uric Acid 87 CRP 129 .
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure weekly maintenance for one of three Chemistry analyzers was performed and documented as required by the manufacturer on five of 10 weeks in March, April, and May 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 07/16/25. 2. A Horiba Pentra 400 analyzer was observed as present and in use during the tour. The laboratory implemented testing using this analyzer on 03/25/25. 3. The manufacturer required weekly ISE module cleaning and weekly needles and mixer cleaning as indicated on the Maintenance Schedule provided by the manufacturer. 4. Weekly maintenance was not performed and documented in two of five weeks in April 2025 and two of four weeks in May 2025 as indicated on the Maintenance Schedule forms found in the untitled purple 3-ring binder. The March 2025 Maintenance Schedule for one of one weeks of testing was not found. The laboratory was unable to provide this document upon request. 5. In an interview at 3:50 p.m. on 07/17/25, TP3 confirmed the above finding. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two levels of quality control material (QC) were performed and acceptable for one of three chemistry analyzers on 13 of 66 days of testing in April, May, and June 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 07/16/25. 2. A Horiba Pentra 400 analyzer was observed as present and in use during the tour. The laboratory implemented testing using this analyzer on 03/25/25. 3. Two levels of acceptable QC was required each day of patient testing as established in the following procedures found in an untitled black 3-ring binder: Aspartate Transferase Horiba Pentra C400 Blood Urea Nitrogen Horiba Pentra C400 Calcium Horiba Pentra C400 Chloride Horiba Pentra C400 Cholesterol HDL Horiba Pentra C400 Creatinine Horiba Pentra C400 Direct Bilirubin Horiba Pentra C400 Glucose Horiba Pentra C400 Magnesium Horiba Pentra C400 Total Bilirubin Horiba Pentra C400 4. At least two levels of acceptable QC were not obtained on multiple days of testing in April, May, and June 2025 as indicated in the Horiba Pentra 400 Monthly QC Results reports found in an untitled purple 3-ring binder. The dates of testing and analytes affected are listed below. Date Analyte 04/01 /25 Blood Urea Nitrogen 04/04/25 Creatinine 04/10/25 Total Bilirubin 04/14/25 Aspartate Transferase Calcium 04/16/25 Magnesium 04/17/25 Creatinine 04/18/25 Cholesterol HDL 04/22/25 Glucose Blood Urea Nitrogen Aspartate Transferase 05/07 /25 Chloride 05/09/25 Cholesterol HDL 05/21/25 Calcium 06/11/25 Direct Bilirubin 06/20/25 Chloride 5. In an interview at 3:20 p.m. on 07/17/25, TP3 confirmed the above finding. 6. In an email received at 9:05 a.m. on 07/18/25, the laboratory indicated a total of 282 patient test results were reported over 13 days of testing when acceptable QC was not obtained for the following dates and analytes: Date Analyte Patients 04/01/25 Blood Urea Nitrogen 8 04/04/25 Creatinine 14 04/10/25 Total Bilirubin 1 04/14/25 Aspartate Transferase 2 Calcium 17 04/16/25 Magnesium 2 04/17 /25 Creatinine 24 04/18/25 Cholesterol HDL 11 04/22/25 Glucose 29 Blood Urea Nitrogen 26 Aspartate Transferase 22 05/07/25 Chloride 35 05/09/25 Cholesterol HDL 27 05/21/25 Calcium 34 06/11/25 Direct Bilirubin 1 06/20/25 Chloride 29 7. Horiba Pentra 400 Monthly QC Reports for April, May, and June were requested at 12:52 p.m. on 07/23/25. In an email received at 2:40 p.m. on 07/23/25, the laboratory provided this information. A summary of unacceptable QC results is below. Date and Analyte Obtained Expected 04/01/25 Blood Urea Nitrogen 15.2 15.3-18.5 04/04/25 Creatinine 0.7 1.0-1.2 Creatinine 2.6 3.6-4.3 04/10/25 Total Bilirubin 0.90 0.93-1.21 Total Bilirubin 3.89 4.00-4.89 04/14/25 Aspartate Transferase 21 41-61 Calcium 0.1 7.7-9.4 04/16/25 Magnesium 2.81 2.82-3.5 04/17/25 Creatinine 0.9 1.0-1.2 Creatinine 3.4 3.6-4.3 04/18/25 Cholesterol HDL 61 63-77 04/22/25 Glucose 106 85-104 Blood Urea Nitrogen 18.9 15.3-18.5 Aspartate Transferase 171 140-170 05/07/25 Chloride -- 78-92 Chloride -- 97-112 05/09/25 Cholesterol HDL 61 63-77 05/21/25 Calcium 0 7.7-9.4 Calcium 12.2 12.3-15.0 06/11/25 Direct Bilirubin 2.38 2.40-2.94 06/20/25 Chloride 76 78-92 .
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 document review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to ensure accurate and reliable test results were reported in 2025. Findings are as follows: 1. The Laboratory Director failed to provide adequate oversight of the laboratory in 2025. See D6004 2. The Laboratory Director failed to ensure all required performance verification (PV) activities were completed for one new chemistry analyzer implemented in 2025. See D6013 3. The Laboratory Director failed to ensure patient test results were reported only when the test systems were functioning properly in 2025. See D6024 .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory director failed to provide adequate oversight of the laboratory in 2025. The laboratory performed approximately 43,050 tests on patient samples annually. Findings are as follows: 1. The laboratory director failed ensure safety procedures were followed for the disposal of biohazardous materials in accordance with applicable Federal, State, and/or local requirements in 2025. See D3011 2. The laboratory director failed to ensure manufacturer instructions were followed for one of two chemistry analyzers in use prior to reporting patient test results in February 2025. See D5411 3. The laboratory director failed to ensure specimen collection materials were not used after the expiration had been exceeded in 2025. See D5417 4. The laboratory director failed to ensure all required performance verification (PV) activities were completed for 24 of 24 analytes on one new chemistry analyzers prior to reporting patient test results in 2025. See D5421 5. The laboratory director failed to ensure weekly maintenance for one of three Chemistry analyzers was performed and documented as required by the manufacturer on 5 of 10 weeks in March, April, and May 2025. See D5431 6. The laboratory director failed to ensure two levels of quality control material (QC) were performed and acceptable on one of three chemistry analyzers on 13 of 66 days of testing in April, May, and June 2025. See D5447 7. The laboratory director failed to ensure the technical consultant evaluated one of one performance verifications and five of five calibration verifications completed in 2025. See D6040 .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure all required performance verification (PV) activities were completed for one of one new chemistry analyzers implemented in 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 07/16/25. 2. A Horiba Pentra 400 analyzer was observed as present and in use during the tour. The laboratory began testing patient specimens using this analyzer on 03/25/25. 3. Performance verification (PV) documentation for the Horiba Pentra 400 analyzer included accuracy data, precision data, and linearity (reportable range) data. 4. Laboratory director approval of the Horiba Pentra 400 PV was not found during review of laboratory records. The laboratory was unable to provide this documentation upon request.. 5. In an interview at 12:25 a.m. on 07/16/25, TP3 confirmed the above finding. 6. In addition, the laboratory director failed to ensure the Horiba Pentra 400 accuracy, reference range, and reportable range verification was completed for each analyte and failed to ensure the technical consultant evaluated the PV data for acceptability prior to reporting patient test results. See D5421 and D6040 .
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory director failed to ensure patient test results were reported only when the test systems were functioning properly in 2025. Findings are as follows: 1. The laboratory director failed to ensure manufacturer instructions were followed for the Tosoh AIA-2000 chemistry analyzer prior to reporting 2 Vitamin D patient test results in February 2025. See D5411 2. The laboratory director failed to ensure all required performance verification (PV) activities were completed for the Horiba Pentra 400 chemistry analyzer prior to reporting patient test results in March through July 2025. See D5421 3. The laboratory director failed to ensure two levels of quality control material (QC) were performed and acceptable on the Horiba Pentra 400 chemistry analyzer prior to reporting patient test results on 13 of 66 days of testing in April through June 2025. See D5447 .
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel,

	the technical consultant failed to evaluate one of one performance verifications (PV) and five of five calibration verifications completed in 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 3 (TP3) during a tour of the laboratory at 8:14 a.m. on 07/16/25. 2. A Horiba Pentra 400 analyzer, a Tosoh AIA-2000 analyzer, and a Tosoh G8 analyzer were observed as present and available use during the tour. 3. The laboratory performed general chemistry and immunology testing on the Horiba Pentra 400, endocrinology testing on the Tosoh AIA-2000 and Hemoglobin A1c testing on the Tosoh G8. 4. Technical consultant evaluation for acceptability was not found during review of the Horiba Pentra 400 PV data. The laboratory was unable to provide this documentation upon request. In addition, the PV documentation for the Horiba Pentra 400 was incomplete. See D5421 for PV non-compliance issues. 5. Technical consultant evaluation for acceptability for one calibration verification performed on the Tosoh G8 analyzer on 04/01/25 (A1c) and four calibration verifications performed on the Tosoh AIA-2000 analyzer on 03/27/25 (Ferrratin, FSH, Prolactin, PSA) was not found during review of laboratory records. 6. In an interview at 12:25 and 12:15 p.m., respectively, on 07/16 /25, TP3 confirmed the above finding. .