Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0724410	01/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lifelink Iii	4188 Lexington Ave N, Saint Paul, 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
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, and interview with laboratory personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings are as follows: 1. The laboratory failed to adequately define quality control (QC) requirements in an Individualized Quality Control Plan (IQCP) in 2022, 2023, and 2024. See D5441 2. The laboratory failed to perform minimum quality control activities required for Chemistry and Hematology testing in 2022, 2023, and 2024. See D5445 .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based document review and interview with laboratory personnel, the laboratory director failed to approve one of four written procedures in use by the laboratory in

	2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing using the BGEM test card on the Siemens epoc blood analysis system as confirmed by the Technical Consultant (TC) during the entrance interview at 10:05 a.m. on 01/23/24 2. Laboratory Director approval of the Universal Patient Care Guideline, which included the standing test authorization, was not found during review on date of survey. 3. In an interview at 2: 00 p.m. on 01/23/24, the TC confirmed the above finding. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to adequately define quality control (QC) requirements in the single Individualized Quality Control Plan (IQCP) in use in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing using the BGEM test card on the Siemens epoc blood analysis system as confirmed by the Technical Consultant (TC) during the entrance interview at 10:05 a.m. on 01/23/24. 2. The Quality Assurance General Procedure, used as the Quality Control Plan of the IQCP, indicated 2 levels of QC material were tested with every new lot or shipment and monthly. 3. The TC indicated two levels of Metabolite QC materials and two levels of Hematacrit QC materials were tested with every new lot or shipment and monthly. 4. In an email received at 1:29 p.m. on 01/26/24, the TC confirmed the above finding. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities required for Chemistry and

	Hematology testing in 2022, 2023, and 2024 on two of three analyzers reviewed. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing using the BGEM test card on the Siemens epoc blood analysis system as confirmed by the Technical Consultant (TC) during the entrance interview at 10:05 a.m. on 01/23/24. 2. The Quality Assurance General Procedure, used as the Quality Control Plan of the Individualized Quality Control Plan (IQCP), indicated 2 levels of QC material were tested with every new lot or shipment and monthly. However, the TC indicated two levels of Metabolite QC materials (L1, L3) and two levels of Hematacrit QC materials (HA, HB) were tested with every new lot or shipment and monthly. See D5441 for incomplete IQCP. 3. QC was not performed as required on two of the three analyzers reviewed in the time period of February 2022 through January 23 2024, as indicated in epoc Enterprise Data Manager reports reviewed on date of survey and provided by the TC on 01/24/24 and 01/25/24. See below. Analyzer 09548 QC data 6/14/22 acceptable 07/14/22 incomplete, missing L1 08/16/22 acceptable No QC performed September - December 2022 Patients tested without QC 07/14/22 - 08/15/22 10 09/16/22 - 12/31/22 12 Analyzer 45685, implemented May 2023 QC data No QC performed June 2023 07/06/23 incomplete, missing L1, L3, HB No QC performed August - October 2023 11/25/23 incomplete, missing L3 No QC performed December 2023 - 01/23/24 Patients tested without QC November 2023 7 December 2023 5 January 2024 1 4. In an interview at 3:35 p.m. on 01/23/24, the TC confirmed the above finding. .
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: . Based on document review and interview with laboratory personnel, the laboratory failed to follow an established quality assurance procedure and failed to correct problems with quality control performance in 2022 and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing using the BGEM test card on the Siemens epoc blood analysis system as confirmed by the Technical Consultant (TC) during the entrance interview at 10:05 a.m. on 01/23 /24 . 2. Quality control (QC) reviews by the TC were required monthly as established in the LifeLink Quality Assessment - 2018 procedure provided by the laboratory. 3. TC1 monthly review of QC data failed to capture missing QC performance and correct problems with QC performance in five months in 2022 and two months in 2023 as shown in the epoc Enterprise Data Manager reports reviewed on date of survey and provided by the TC on 01/25/24 and 01/26/24. See D5445. 4. Testing was performed on 22 patients in 2022 and on 12 patients in 2023 without the required QC. 5. In an interview at 3:35 p.m. on 01/23/23, the TC confirmed the above finding. .
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 review of laboratory policies and procedures, quality control logs, and previous survey data, the Laboratory Director failed to ensure previously cited deficiencies were corrected. Findings are as follows: The following deficiency was cited during the 09/16/16 and 04/11/18 surveys and was also out of compliance on 01 /23/24. D5445 - the laboratory failed to perform minimum quality control activities required for Chemistry and Hematology testing. .
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 review of laboratory policies and procedures, quality control logs, and interview with laboratory personnel, the Laboratory Director failed to ensure quality control (QC) requirements were followed in 2022, 2023, and 2024. Findings are as follows: QC was not performed as required on two of the three analyzers reviewed in the time period of February 2022 through January 23 2024. Testing was performed on 22 patients in 2022, on 12 patients in 2023, and on 1 patient in 2024 without required QC. See D5445. .
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure each and every 2022 competency assessments included a problem solving assessment for the single moderate complexity test performed by the laboratory. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry and Hematology testing using the BGEM test card on the Siemens epoc blood analysis system as confirmed by Technical Consultant 1 during the entrance interview at 10:05 a.m. on 01/23/24. 2. 2022 competency

	assessment documents reviewed for 97 of 97 testing personnel (TP) did not include problem solving evaluations for the BGEM test . 3. In an interview at 10:50 a.m. on 01 /23/24, Technical Consultant 2 confirmed the above finding. .