Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	24D0724410	04/11/2018
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure all personnel who routinely performed patient testing were included in testing proficiency testing samples. Findings are as follows: 1. The laboratory performed proficiency testing (PT) for Chemistry and Hematology using the American Proficiency Institute (API) proficiency testing provider. 2. Review of PT records from API indicated the Clinical Service Manager (CSM) and one testing personnel performed all testing of PT samples in the time period reviewed, September 2016 through March 2018. 3. The Laboratory Personnel Report (CLIA) Form CMS-209 listed a total of twenty four testing personnel for the laboratory. 4. In an interview on 04/11/18 at 2:55 p.m., the CSM confirmed the above finding.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory

	failed to ensure functions checks for the Chemistry and Hematology analyzers were completed as required. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Clinical Services Manager (CSM) during the entrance conference on 04/11/18 at 1:00 p.m. The CSM stated the laboratory had 10 epoc Blood Analysis Systems in use and located at satellite bases throughout Minnesota. 2. A requirement for twice annual verification of the thermal control system was established in the Quality Assurance General Procedure located in the electronic procedures file. 3. Laboratory records indicated the thermal control system for 8 of 10 epoc Blood Analysis Systems was not verified twice annually in the timeframe reviewed; January 2016 to March 2018. See below Thermal control verification dates System 2016-1 2016-2 2017-1 2017-2 2018-1 14180 3/16 12/17 15934 12/17 2/18 15937 2/16 4/17 12/17 15939 2/16 3/17 12/17 15941 12/17 15952 2 /16 10/16 12/17 15983 2/16 12/17 18798 3/17 12/17 3/18 4. In an interview on 04/11 /18 at 3:30 p.m., the Technical Consultant confirmed the thermal system verifications had not been performed at least twice annually as required.
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 quality control procedures for Chemistry and Hematology testing using the frequency and quantity established by the laboratory. In addition, the laboratory failed to perform quality control as required by the manufacturer. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the Clinical Services Manager (CSM) during the entrance conference on 04/11/18 at 1:00 p.m. The CSM stated the laboratory had 10 epoc Blood Analysis Systems located at satellite bases throughout Minnesota. A. Quality Control frequency and quantity 1. External quality control (QC) for the epoc Blood Analysis System was required using 2 levels of control material for new lots or shipments of testing cards and every 30 days as indicated in the laboratory's Individualized Quality Control Plan (IQCP). 2. Review of epoc Blood Analysis System online QC records for 2 of 10 devices in the time period of September 2016 through March 2018 indicated QC was not consistently performed using the frequency established by the laboratory. See below System QC dates Days elapsed 15939 4/21/17, 6/8/17 49 15952 12/21/16, 2/23 /17 65 3. Laboratory records also indicated QC was not consistently performed with the quantity of control materials established by the laboratory. See below System QC dates Missing level 15952 4/29/17 L1 8/26/17 L3 4. In an interview on 04/11/18 at 3: 55 p.m., the Technical Consultant (TC) confirmed QC had not been performed as establishes in the laboratory's IQCP. *This is a repeat citation from 09/16/16 survey* B. Manufacturer's Quality Control requirements 1. The QA section of the manufacturer's epoc System Manual, dated 2010, indicated 2 levels of control material must be tested in duplicate prior to use of new lots and new shipments of testing

	cards. 2. The laboratory's IQCP did not include duplicate testing of QC materials. 3. Review of epoc Blood Analysis System online QC records for 2 of 10 devices in the time period of September 2016 through March 2018 indicated QC was not performed in duplicate by the laboratory. 4. In an interview on 04/11/18 at 3:10 p.m., the TC confirmed QC was not performed in duplicate as required by the manufacturer.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 3 of 18 new testing personnel trained between 11/10/16 and 08/31/17. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Clinical Services Manager (CSM) during the entrance conference on 04/11/18 at 1:00 p.m. 2. Testing Personnel 16, 17 and 21 (TP16, TP17 and TP21) were listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as full time employees performing moderate complexity testing. 3. Laboratory records indicated the testing personnel were trained and initially assessed for testing competency as listed below. TP Initial competency date TP16 05 /17/17 TP17 05/24/17 TP21 08/02/17 4. Semiannual competency assessments for the these testing personnel were not found during review of laboratory records on date of survey, 04/11/18. The laboratory was unable to provide the missing competency assessment documents upon request. 5. In an interview on 04/11/18 at 1:55 p.m., the CSM confirmed the semiannual competency assessments for TP16, TP17 and TP21 had not been completed.