Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1008469	05/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lifebanc	4775 Richmond Road, Cleveland, OH	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to meet the requirements in the subspecialty of routine chemistry as specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel (TP) as well as the assessment of the Clinical Consultant (CC) and Technical Consultant (TC) based on the responsibilities of their positions. (Refer to D5209) 2. The laboratory failed to perform quality control (QC) procedures as required and specified by the CLIA regulations, manufacturer's instructions or established by the laboratory prior to implementation of an Individualized Quality Control Plan (IQCP). (Refer to D5445) 3. The laboratory failed to, each day of patient testing, perform and document quantitative blood gas quality control (QC) procedures, to include two levels of QC material of different concentrations. (Refer to D5447) 4. The laboratory failed to include the positive patient identification of the blood gas specimens in the test records. (Refer to D5787) 5. The laboratory failed to have an adequate manual system in place to ensure the blood gas testing results were accurately and reliably documented on the final test report. (Refer to D5801) 6. The laboratory failed to indicate the name and address of the laboratory location where all laboratory testing was performed and the units of measurement (UOM) for each of the tested analytes reported on the final test report. (Refer to D5805)
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel (TP) as well as the assessment of the Clinical Consultant (CC) and Technical Consultant (TC) based on the responsibilities of their positions. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 05/14/2018, revealed 17 individuals listed as TP, one individual listed as a CC and one individual listed as a TC. 2. Review of the laboratory's policies and procedures, approved via signature and date by the Laboratory Director and provided on the date of the inspection, did not find a competency assessment policy and procedure. 3. Further review of the laboratory's policies and procedures, provided on the date of the inspection, revealed an "iStat Proficiency Testing" policy that revealed the following section: "III. Procedure A. Employee Training and Competency 1. New users will receive training and education... 2. New users will have an initial training and competency...6 months after the initial training and...annual... 3. ...training may included; reviewing the iStat protocol in the Learning Management System (LMS), a return demonstration and practice session, and/or completion of the written competency exam in the learning management system... 4. ...each user will have an observed competency performed by the Organ Services Manager and or Supervisor... 5. Proficiency testing (PT)...will be rotated among all trained users... 6. All reagents and equipment will be monitored for optimal performance..." 4. The Surveyor requested the laboratory's TP competency assessment policies and procedures to include the six components (required by CLIA), the assessment frequencies and conducted by a qualified TC, the CC and TC competency assessment policies and procedures to include the components assessed (required by CLIA), the assessment frequencies and conducted by a qualified individual, as well as all of the 2017 and 2018 competency assessment documentation from the Laboratory Director. The Laboratory Director confirmed that the laboratory did not establish and follow a competency assessment policy and procedure for the assessment of the TP, CC and TC did not directly observe TP collecting/handling /testing a patient sample, did not include all of the six required components in the assessment of the TP, did not assess the CC and TC based on the responsibilities of each of the positions, did not assess the competencies by qualified individuals and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/15/2018 at 1:17 PM.
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 record review and an interview with the Laboratory Director, the laboratory failed to perform quality control (QC) procedures as required and specified by the CLIA regulations, manufacturer's instructions or established by the laboratory prior to implementation of an Individualized Quality Control Plan (IQCP). Findings Include:
1. Review of the laboratory's "QA Process for the iStat" policy and procedure, approved, signed and dated by the Laboratory Director and provided on the date of the inspection, found the following QC instructions: "C. Periodic Procedures 1. Analyzer QC... a. ...the Electronic Simulator before every donor case and every eight hours afterward... 4. Monthly QC a. Monthly QC will be performed every month between the 1at and the 7th day of the month. b. Tri-controls control solutions Level 1 and Level 3 must be run for each iStat machine and each cartridge type every month... c. The Monthly QC must be documented..." QA; quality assessment 2. Review of the laboratory's "IQCP Risk Assessment for Lifebanc Organ Donor Management Utilizing iStat System" document, provided on the date of the inspection, found the following statements: "Analytic phase: The following are risk mitigation procedures performed by our point of care laboratory to reduce the incidence of analytic errors. ... 6. The I-stat test system performs timed steps at the required intervals and has a lock out feature that will not allow operation if function checks fail. a. The internal Electronic Simulator is performed every 8 hours or with the insertion of each cartridge. b. If the internal Electronic Simulator fails, the external Electronic Simulator test must be performed. c. Two levels of liquid quality control are performed with each shipment or new lot number of cartridges...every 30 days, according to manufacturer's recommendations..." 3. Review of the laboratory's 2017 performance verification, 2017 and 2018 Electronic Simulator (ES) and QC records, provided on the date of the inspection, revealed the laboratory did not perform and document any study to support the IQCP implemented, did not perform and document the ES on the specific iStat analyzer used on each day of patient testing, did not perform two levels of liquid QC on each shipment and new lot number of CG4+ cartridges on each of the two iStat analyzers used for patient testing prior to testing patient samples and did not perform 2 levels of liquid QC on the specific iStat analyzer used each day of patient testing as indicated below: Patient Test 03/22/18 on iStat SN 387693 ES not tested/documented 2 levels of QC not tested/documented Patient Test 03/28/18 on iStat SN 387693 ES tested/documented for one unknown SN 2 levels of QC not tested/documented Patient Test 04/04/18 on iStat SN 387693 ES not tested/documented 2 levels of QC not tested/documented Patient Test 04/10/18 on iStat SN 387609 ES not tested/documented 2 levels of QC not tested/documented Patient Test 04/17/18 on iStat SN 387609 2 levels of QC not tested/documented Level 1 liquid QC (lot number 301100) only tested/documented for one unknown IStat SN on 01/18/2018 Level 3 liquid QC (lot number 321094) only tested/documented for one unknown IStat SN on 01/18/2018 SN; serial number 4. Further review of the laboratory's 2018 "iStat Monthly QC" records revealed the following: Date of QC level Testing Tested 03/05/18 Level 3 03/19/18 Level 1 04/05/18 Levels 1/3 05/03/18 Levels 1/3 5. The Surveyor requested the laboratory's complete IQCP documentation, to include the Risk Assessment (RA) (addressing all of the required components), the Quality Control Plan (QCP) with supporting historical data and the Quality Assessment (QA) plan as well as all of the laboratory's 2018 ES and QC documentation from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish a complete RA, QCP and QA plan, did not perform any additional activities to support the IQCP implemented, did not test/document ES and 2

	levels of QC testing on each IStat analyzer used on each day of patient testing, as required, did not follow their written monthly QC protocol in March 2018 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/15/2018 at 10:35 AM.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to, each day of patient testing, perform and document quantitative blood gas quality control (QC) procedures, to include two levels of QC material of different concentrations. Findings Include: 1. Review of the laboratory's "QA Process for the iStat" policy and procedure, approved, signed and dated by the Laboratory Director and provided on the date of the inspection, did not find any instructions to perform and document two levels of QC material of different concentrations each day of patient testing. 2. Review of the laboratory's 2018 Electronic Simulator (ES) and QC records, provided on the date of the inspection, found that the laboratory did not perform and document the ES and two levels of QC material on the specific iStat analyzer used on each day of patient testing. 3. The Surveyor requested the laboratory's 2018 ES and QC documentation from the Laboratory Director. The Laboratory Director confirmed the laboratory did not test/document ES and 2 levels of QC testing on each IStat analyzer used on each day of patient testing, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/15/2018 at 10:35 AM.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to include the positive patient identification of the blood gas specimens in the test records. Findings Include: 1. Review of all five of the laboratory's test records since the laboratory began testing on 03/22/2018 and provided on the date of the inspection, found the blood gas results were printed on roll thermal paper directly from the IStat test system with no patient name, identification number or any other indication of positive patient identification. 2. The Laboratory Director confirmed the laboratory did not follow established protocols for entering positive patient

	identification information into the IStat test system so it would be indicated on the IStat analyzer result printout. The interview occurred on 03/15/2018 at 11:11 AM.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to have an adequate manual system in place to ensure the blood gas testing results were accurately and reliably documented on the final test report. Findings Include: 1. Review of all five of the laboratory's test records and test reports since the laboratory began testing on 03/22/2018, provided on the date of the inspection, revealed the bicarbonate (HCO3) result for one out of the five test records/reports was transcribed into the final test report inaccurately as follow: I-Stat CG4+ analyzer printout HCO3 23.2 mmol/L Arterial Blood Gases test report HCO3 23.4 2. The Laboratory Director confirmed the patient's HCO3 result was manually entered into the patient's electronic chart inaccurately. The interview occurred on 03/15/2018 at 11: 11 AM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to indicate the name and address of the laboratory location where all laboratory testing was performed and the units of measurement (UOM) for each of the tested analytes reported on the final test report. Findings Include: 1. Review of all five of the laboratory's test reports since the laboratory began testing on 03/22/2018 and provided on the date of the inspection, found blood gas and other laboratory test results documented that were tested and reported prior to the patients' transfer to the organ donor facility, however did not find the name and address of the laboratory location where the laboratory testing was performed when not tested on site. 2. Further review of the laboratory's five test reports did not find the UOM for each of the blood gas

	analytes (pH, pCO2, pO2, HCO3 and O2sat) reported. pCO2; partial pressure of carbon dioxide pO2; partial pressure of oxygen HCO3; bicarbonate O2sat; oxygen saturation 3. The Laboratory Director confirmed the patients' test reports did not include the name and address of the laboratory location where the testing was performed when not tested on site. The interview occurred on 03/15/2018 at 11:11 AM.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that an effective quality assessment program was established and maintained to assure the quality of the blood gas testing provided. Findings Include: 1. Review of the laboratory's "QA Process for the iStat" policy and procedure, approved, signed and dated by the Laboratory Director and provided on the date of the inspection, did not find instructions for quality assessment activities to include what monitors are to be reviewed in each phase of the blood gas testing process (general laboratory system, preanalytic, analytic and post analytic), the frequency of the assessments, how problems are identified and documented, what and how corrective action measures are implemented and the review of the effectiveness of the corrective action implemented. 2. Review of the laboratory's five blood gas test records and test reports since the laboratory began testing on 03/22/2018, provided on the date of the inspection, revealed the bicarbonate (HCO3) result for one out of the five test records/reports was transcribed into the final test report inaccurately, as follows, and was not identified: I-Stat CG4+ analyzer printout HCO3 23.2 mmol/L Arterial Blood Gases test report HCO3 23.4 3. The Laboratory Director stated that the quality assessment process is an all inclusive review of the patient chart. The Laboratory Director confirmed the patient's HCO3 result was manually entered into the patient's electronic chart inaccurately and that the error was not identified in the quality assessment process. The interview occurred on 03/15/2018 at 1:35 PM.