Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0921245	06/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Donor Alliance, Inc	8175 E 1st Ave, Denver, CO	

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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on a record review and interview with the laboratory director (LD), the laboratory failed to document and retain the risk assessment (RA) for the Abbott i-STAT when implementing an Individualized Quality Control Plan (IQCP) in 2016. Findings include: a. The LD stated that the laboratory had completed an IQCP for the i-STAT analyzer. b. The surveyor requested the i-STAT IQCP documentation from the LD. c. The LD provided a one-page IQCP summary for the i-STAT analyzer, and was unable to produce documentation of the RA to the surveyor. d. On 6-27-18 at around 3:30 p.m., the LD stated the RA had not been retained, and confirmed the laboratory had no documentation of the RA for the Abbott i-STAT analyzer to support their IQCP decisions.
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 a record review and interview with the laboratory director (LD), the laboratory failed to include two of the five required components in the risk assessment (RA) for the Instrumentation Laboratory (IL) GEM Premier 4000 chemistry analyzer when implementing an Individualized Quality Control Plan (IQCP) in 2016. Findings include: a. The laboratory tests sodium, potassium, chloride, glucose, total hemoglobin, lactate, ionized calcium, and blood gases (pH, pO2, pCO2) using the IL GEM Premier 4000 chemistry analyzer. b. Review of the RA records for the GEM Premier 4000 chemistry analyzer showed that the laboratory accepted the risk assessment provided by the manufacturer, but the RA did not include the components of laboratory personnel or environment. c. On 6-27-18 at about 3 p.m., the LD stated they were unaware that the RA obtained from the IL GEM manufacturer did not include all required components, and confirmed that the laboratory had not assessed the components of personnel and environment for their IQCP as required by the federal CLIA regulations.
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: 1 Based on the review of an incomplete Individualized Quality Control Plan (IQCP), quality control (QC) records, and laboratory director interivew, the laboratory failed in 2018 to test one sample of control material each eight hours of testing using a combination of control materials that include both low and high values every day that patient specimens are tested for blood gases using the Abbott i-STAT chemistry analyzer. a. The laboratory tests patient specimens for blood gas levels (pH, pO2, pCO2) using the Abbott i-STAT chemistry analyzer. b. The laboratory provided an incomplete IQCP for the i-STAT analyzer where the risk assessment (RA) component had not been retained to support their IQCP decisions. d. Review of QC records for the i-STAT analyzer showed external control materials were tested monthly in 2018 and 226 patients were tested on days when QC had not been tested (Jan=38, Feb=36, Mar=63, Apr=21, May=32, June=36). e. On 6-27-18 at about 3:30 p.m., the laboratory director stated she was unaware that the IQCP for the i-STAT analyzer was incomplete, and confirmed that external controls for the chemistry analyzer had not been tested each day of patient testing until the IQCP would be complete as required by federal CLIA regulation. 2. Based on a review of an incomplete Individualized Quality Control Plan (IQCP), quality control (QC) records, and laboratory director interview, the laboratory failed in 2018 to test one sample of control material each eight hours of testing using a combination of control materials that include both low and high values every day that patient specimens are tested for blood gases using the GEM Premier 400 chemistry analyzer. a. The laboratory tests patient specimens for blood gas levels (pH, pO2, pCO2) using the Instrumentation Laboratory (IL) GEM Premier 400 chemistry analyzer. b. The laboratory provided an incomplete IQCP for the GEM analyzer where the risk assessment (RA) contained three of the five required

	components but did not contain an assessment of laboratory personnel and environment. c. Review of the QC records for the GEM analyzer showed external control materials were tested monthly in 2018 and 17 patients were tested on days when QC had not been tested (Jan=1, Feb=4, Mar=3, Apr=4, May=4, June=1). d. On 6-27-18 at about 3:30 p.m., the laboratory director stated she was unaware that the IQCP for the GEM analyzer was incomplete, and confirmed that external controls for the chemistry analyzer had not been tested each day of patient testing until the IQCP would be complete as required by federal CLIA regulation.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a lack of comparison documentation and lab director (LD) interview, the laboratory failed to conduct a comparison of general chemistry test results at least twice yearly in 2016, 2017, and 2018 to ensure equitable results between three in-use Abbott i-STAT chemistry analyzers. Findings include: a. The laboratory tests patient specimens for blood gases (pH, pO2, pCO2), lactate, Creatine phosphokinase MB isoenzyme (CK-MB), troponin, and prothrombin time/international normalized ratio (PT/INR) using the Abbott i-STAT chemistry analyzer. b. There are three in-use i-STAT analyzers in the laboratory. c. The surveyor requested documentation showing the three i-STATs had been compared twice yearly to ensure equitable test results between the analyzers. d. The LD stated they were aware of the regulatory requirement but unaware which type of samples could be used for comparison testing. e. On 6-27-18 at around 2:30 p.m., the LD confirmed the laboratory had not compared any chemistry test results between the three i-STAT analyzers as required by the federal CLIA regulations.