

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1005205	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Indiana Donor Network	Street Address, City, State 3760 Guion Road, Indianapolis, IN	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to keep quality control records for seven of eight patient test reports reviewed for blood gas and prothrombin analysis. Findings include: 1) Review of policy titled, "Portable Laboratory Testing Quality Assurance Plan," policy number-"7.000," dated "08/18/2020," no laboratory director signature indicated, read on page 1 of 11, "This policy will be specific for Point of Care testing performed by the Organ Services department utilizing the i-STAT portable analyzer....Functional services available include: Blood gases (pH, pCO2, pO2...Prothrombin Time..." The policy further states on page 6 of 11, "...Equivalent liquid control testing must be performed to verify that all internal controls are working properly...Liquid controls must be run after new cartridge lots are received, after major maintenance or replacement of critical parts. If these tests are acceptable, the lab can continue to perform monthly equivalent liquid testing..." Legend: pH=power of hydrogen pCO2=partial pressure of carbon dioxide pO2=partial pressure of oxygen PT=prothrombin time 2) Medical record review indicated the following patients had blood gas and prothrombin analysis performed on the i-Stats (Patients 2-8): Patient # Date Result PT2: 2/14/20 pH=7.28 PT3: 3/28/20 pH=7.46 PT4: 4/14/20 pH=7.38 PT5: 2/06/19 PT=18.8 seconds PT6: 4/03/19 PT=16.5 seconds PT7: 11/10/19 pH=7.39 PT8: 12/19/19 pH=7.34 3) In interview on 10/07/20 at 4:11 pm, SP-2 confirmed quality control data for blood gas and prothrombin testing on the i-Stats would not be available for review for the months of February 2019 and 2020, April 2019 and 2020, November 2019, December 2019, and March 2020. The documentation was not retained for a minimum of two years. 4) Total annual testing</p>

volume for arterial blood gases=3,500 Total annual testing volume for prothrombin times=250