

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1005205	(X3) Date Survey Completed 06/22/2022
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to enroll in an approved Proficiency Testing (PT) program in 2021 for eight of eight analytes [blood urea nitrogen (BUN), creatinine, sodium (NA), potassium (K+), chloride (Cl), glucose, creatinine (Crea) and Hematocrit (Hct)] tested using the I-Stat CHEM8+ (blue) cartridge in the subspecialties of Routine Chemistry and Hematology. Findings include: 1) On 06/22/22 at 10:45 am, during the tour of the laboratory an i-Stat was observed to be available for use in the laboratory. 2) Review of policy titled, "Portable Laboratory Testing Device", effective date: 06/07/22 with no laboratory director signature, states (under i-STAT Process Standards) on page 1 of 10, "Annual critical evaluation will include review of proficiency test reporting and recording". 3) In interview on 06/22/22 at 2:25pm, SP-8 confirmed the laboratory was using the CHEM8+ (blue) cartridge and tests BUN, NA, K+, CL, glucose, creatinine, and hematocrit. SP-8 (Organ Supervisor) further acknowledged the laboratory was not enrolled in proficiency testing (PT) for these analytes in 2021. 4) Review of the Federal Drug Administration Clinical Laboratory Improvement Amendments (CLIA) data base for test categorization i-STAT BLUE CHEM8+ Cartridge for BUN, NA, K+, Cl, glucose, creatinine, and hematocrit is categorized as moderate complex</p>

effective 2/7/2020. 5) Review of patient medical records indicates the following patients were testing for chloride (Cl) and glucose without PT being performed in 2021: PT# 1 on 06/09/21 - Result: chloride 135 mmol/L PT# 3 on 01/16/21 - Result: glucose 193mmol/L 5) Annual Test Volume for the subspecialty of Routine Chemistry is 2,068.