Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1005205	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Indiana Donor Network	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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory failed to successfully participate in the College of American Pathologists (CAP) proficiency testing (PT) program for three of eight analytes (chloride, glucose, and sodium) tested in the subspecialty of Routine Chemistry. The laboratory had unsatisfactory overall PT event testing scores (less than 80%) for two consecutive PT testing events in 2022 (Event 1, 2022 and Event 3, 2022) (Refer to D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve a satisfactory performance (80% or greater) for two consecutive testing events (event 1, 2022 and event 2, 2022) in Routine Chemistry for three of eight analytes (chloride, glucose, sodium) tested. Findings include: 1) Review of "Casper Report 0155D," indicated the following scores: a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) Event 2, 2022 chloride 60%, glucose 40%, sodium 40% 2) In email communication on 8/17 /22 at 10:56 am, SP-8 (Organ Supervisor/Testing person) confirmed the following scores: a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) Event 2, 2022 chloride 60%, glucose 40%, sodium 40% 3) Review of the "C-B 2022 General Chemistry/Therapeutic Drugs" PT Evaluation with the original evaluation date of 7/8 /2022 from College of American Pathologist confirmed the following scores: a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) Event 2, 2022 chloride 60%, glucose 40%, sodium 40% This document further indicated these analytes had "unsatisfactory" performance.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in the College of American Pathologists (CAP) proficiency testing (PT) program for three of eight analytes (chloride, glucose, and sodium) tested in the subspecialty of Routine Chemistry. The laboratory had unsatisfactory overall PT event testing scores (less than 80%) for two consecutive PT testing events in 2022 (Event 1, 2022 and Event 3, 2022). The laboratory director also failed to ensure that the laboratory enrolled in a Proficiency Testing program for the same analytes (chloride, glucose, and sodium) for 2021. (Refer to D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the

	laboratory successfully participated in the College of American Pathologists (CAP) proficiency testing (PT) program for three of eight analytes (chloride, glucose, and sodium) tested in the subspecialty of Routine Chemistry. The laboratory had unsatisfactory overall PT event testing scores (less than 80%) for two consecutive PT testing events in 2022 (Event 1, 2022 and Event 3, 2022). resulting in unsuccessful performance. The laboratory director also failed to ensure that the laboratory enrolled in a Proficiency Testing program for the same analytes (chloride, glucose, and sodium) for 2021. Findings included: 1) Review of "Casper Report 0155D," indicated the following scores: a) Event 2, 2021 chloride no scores received, glucose no scores received, and sodium no scores received. b) Event 3, 2021 chloride no scores received, glucose no scores received, and sodium no scores received. a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) Event 2, 2022 chloride 60%, glucose 40%, sodium 40% 2) In interview on 06/22/22 at 2:25pm, SP-8 (Organ Supervisor /Testing person) confirmed the laboratory was using the CHEM8+ (blue) cartridge and tests Blood Urea Nitrogen (BUN), sodium (NA), Potassium (K+), chloride (CL), glucose, creatinine, and hematocrit. SP-8 further acknowledged the laboratory was not enrolled in proficiency testing (PT) for these analytes in 2021. 3) In email communication on 8/17/22 at 10:56 am, SP-8 confirmed the following scores: a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) Event 2, 2022 chloride 60%, glucose 40%, sodium 40% 4) Review of the "C-A 2022 General Chemistry /Therapeutic Drugs" PT Evaluation with the original evaluation date of 4/8/2022 and revision evaluation date of 4/12/2022 from College of American Pathologist confirmed the following scores: a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) This document further indicated these analytes had "unsatisfactory" performance, and shows chloride, glucose and sodium were not tested during event 2, 2021 and event 3, 2021. 5) Review of the "C-B 2022 General Chemistry/Therapeutic Drugs" PT Evaluation with the original evaluation date of 7/8/2022 from College of American Pathologist confirmed the following scores: a) Event 1, 2022 chloride 60%, glucose 60%, sodium 60% b) Event 2, 2022 chloride 60%, glucose 40%, sodium 40% c) This document further indicated these analytes had "unsatisfactory" performance, and shows chloride, glucose and sodium were not tested during event 3, 2021.