Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0993441	08/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Diabetes & Endocrine Institute	2610 Courthouse Circle, Flowood, MS	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing and verification of accuracy records since 1/14/2022, interview with the technical consultant on 8/28/2023 at 3:10 p.m., and lack of documentation of verification of accuracy for urine microalbumin and creatinine testing, the laboratory failed to verify the accuracy of urine microalbumin and creatinine testing since patient testing began on 2/1/2023. Findings include: 1. Review of proficiency testing and verification of accuracy records since since the last survey on 1/14/2022 revealed the laboratory was not enrolled in proficiency testing for urine microalbumin and creatinine testing, and there was no documentation of verification of accuracy for urine microalbumin and creatinine testing. 2. In an interview on 8/28/2023 at 3:10 p.m., the technical consultant confirmed the laboratory failed to verify the accuracy of urine microalbumin and creatinine testing since patient testing began on 2/1/2023. At least twice annually, the laboratory must verify the accuracy of any test it performs that is not included in subpart I of this part.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of quality control records and patient test counts for the Beckman Coulter Access 2 immunoassay system, interview with the technical consultant on 8/28 /2023 at 11:30 a.m., and lack of documentation of verification of performance specifications for Vitamin B12 testing, the laboratory failed to verify the manufacturer's performance specifications for Vitamin B12 testing before patient testing began on 8/23/2022. Findings include: 1. Review of quality control records for the Beckman Coulter Access 2 immunoassay system and interview with the technical consultant on 8/28/2023 at 11:30 a.m. revealed Vitamin B12 testing was added to the Beckman Coulter Access 2 immunoassay system on 8/23/22. 2. On 8/28/2023 there was no documentation of verification of performance specifications for Vitamin B12 testing available for review, to include accuracy, precision, and reportable range of test results. 3. In an interview at 11:30 a.m. on 8/28/2023, the technical consultant confirmed verification of performance specifications for Vitamin B12 was not performed before patient Vitamin B12 testing began on 8/23/2022. The laboratory's annual patient test count for Vitamin B12 testing was 1,082. B. Based on review of quality control records and the patient test log for urine microalbumin and creatinine testing from 2/1/2023 through 8/24/2023 on the Siemens DCA Vantage analyzers, interview with the technical consultant on 8/28/2023 at 1:15 p.m., and lack of documentation of verification of performance specifications, the laboratory failed to verify the manufacturer's performance specifications for microalbumin and creatinine testing on two of two Siemens DCA Vantage analyzers before patient testing began on 2/1/2023. Findings include: 1. Review of quality control records and the patient test log for urine microalbumin and creatinine testing from 2/1/2023 through 8/24 /2023 on the two Siemens DCA Vantage analyzers revealed patient urine microalbumin and creatinine testing began on 2/1/23. 2. On 8/28/2023, there was no documentation of verification of performance specifications for urine microalbumin and creatinine testing available for review, to include accuracy, precision, and reportable range of test results. 3. In an interview on 8/28/2023 at 1:15 p.m., the technical consultant confirmed verification of performance specifications for microalbumin and creatinine testing on two of two Siemens DCA Vantage analyzers was not performed before patient urine microalbumin and creatinine testing began on 2 /1/2023. 4. Review of the patient test log for the Siemens DCA Vantage analyzers revealed 773 patient microalbumin/creatinine ratio results were reported from 2/1 /2023 through 8/24/2023.
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 review of the patient test log for urine microalbumin and creatinine testing from 2/1/2023 through 8/24/2023 and interview with the technical consultant on 8/28

	/2023 at 1:40 p.m., the laboratory failed to maintain a record system that included the identity of the personnel who performed urine microalbumin and creatinine testing for 773 of the 773 patient tests performed during this time frame. Findings include: 1. Review of the patient test log for urine microalbumin and creatinine testing from 2/1 /2023 through 8/24/2023 revealed no documentation of the identity of the personnel who performed urine microalbumin and creatinine testing for 773 of the 773 patient tests performed during this time frame. 2. In an interview on 8/28/2023 at 1:40 p.m., the technical consultant confirmed that there was no documentation of the testing personnel for the 773 patient urine microalbumin and creatinine tests performed from 2/1/2023 through 8/24/2023.