Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0646470	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Doctor's Data, Inc	3755 Illinois Avenue, Saint Charles, IL	

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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of annual test volumes; patients' test reports; and interviews with the owner of the laboratory and technical supervisor, the test report did not include the name and address of the laboratory location where the test was performed. Findings: 1. Review of worksheets of the laboratory's tests volumes for tests performed in 2017submitted to the surveyor on October 10, 2018, the laboratory performed a total of 13, 621 Saliva Hormone tests. 2. On September 10, 2018 at 3:00 PM, the surveyor performed a look back of patients' tests. Review of patients' test reports revealed that there was a different test report generated for Adrenal Hormone Reports for saliva. The surveyor observed that the name "Labrix" was used as the company logo on the heading for Adrenal Hormone Reports for saliva. However, the name Doctor's Data Inc was used on the company logo for all other testing. The address location for both was that of Doctor's Data. The surveyor could not determine if "Labrix" was even a laboratory. 3. On October 10, 2018 at 3:30 PM, the owner of the laboratory and the technical supervisor confirmed the surveyor's findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; test runs; test reports; and interview with the technical supervisor, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. Findings include: 1. Review of the laboratory's procedures for reporting Serum Calcium on the Beckman Coulter AU680 Analyzer revealed, in a section titled: "Calculations, " it states, "The instrument reports the serum calcium concentrations directly in the unit of mg/dL and hence no calculation is needed. For reporting calcium in SI units of mmol/L, results in mg/dL are multiplied by 0.25. 2. Review of test run data revealed that tests were reporting in units of mg/dL, while actual patients' test results were reported in mmol/L in the laboratory's information system (LIS). 3. There was no documentation to show that the laboratory periodically verified the accuracy of the calculated data interfaced in its LIS. 4. On October 10, 2018 at 3:00 PM, the technical supervisor confirmed the surveyor's findings.