Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D0646470	**(X3) Date Survey Completed** 11/08/2024
Name of Provider or Supplier Doctor's Data, Inc	**Street Address, City, State** 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**
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation and interview with the technical supervisor (TS), the laboratory failed to discontinue use of one of one synthetic urine concentrate (RICCA, Lot #1102B58) past the date of expiration (August 2022) for urine elements toxicology testing from 10/01/2022 to 11/08/2024, affecting more than 2,271,820 patient tests. Findings include: 1. Review the "Doctor's Data, Inc. Elements in Urine using the ESI Inline prepFAST and Agilent 8900 ICP-QQQ" procedure manual revealed the following information: "Equipment Calibration /Maintenance (cont.) ...Table 24. Pre Calibration Wash ... Wash Solution ...Synthetic urine pool is used in vial #8 to condition the system ..." 2. During the laboratory tour on 11/08/2024, at 9:57 a.m., the surveyor identified one of one synthetic urine concentrate "RICCA, 20L, Lot #1102B58, EXP Aug 2022" utilized for urine elements toxicology testing that exceeded the expiration date, affecting more than 2,271,820 patient tests. 3. On 11/08/2024, at 9:57 a.m., an interview with the TS confirmed the expired synthetic urine concentrate "RICCA, 20L, Lot #1102B58, EXP Aug 2022" utilized for the analytic process of urine elements in toxicology.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test

	system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to establish the performance specifications for three of three analyzers (Agilent Technologies 6460 Triple Quad LC/MS, Model Number: G6490A, Serial Number: SG1325A204, Agilent Technologies 6495 Triple Quad LC/MS, Model Number: G6495A, Serial Number: SG1709D003, Agilent Technologies 6495 Triple Quad LC/MS, Model Number: G6495A, Serial Number: SG1606D002) utilized for lab developed test (LDT) Hormone & Urinary Metabolites Assessment Profile (HuMap) prior to reporting patient test results in 06/2022 to 11/08/2024, affecting 341,586 patient tests. Findings include: 1. Review of the laboratory's "RD-P-105 (version 4.1) Test Performance Validation of Quantitative and Semiquatitative Analysis" policy revealed the following information. "To define the methodology at Doctor's Data Inc. (DOI) for validating a diagnostic kit that has been modified, or a method developed at DOI for determining the quantity of an analyte or measurand. CLIA'88 requires that before any patient samples are analyzed, the following parameters be evaluated for quantitative or semiquantitative analyses. 1. Accuracy 2. Precision 3. Analytical sensitivity 4. Analytical specificity to include interfering substances 5. Reportable range of test results for the test system 6. Reference intervals (normal values) 7. Any other performance characteristics required for adequate test performance" 2. During the laboratory tour on 11/08/2024, at 11:21 a.m., the surveyor identified three analyzers (Serial Number: SG1325A204, Serial Number: SG1709D003, Serial Number: SG1606D002) utilized for LDT Hormone & Urinary Metabolites Assessment Profile (HuMap) testing. 3. Review of the "Validation of Urinary Steroids Hormones by LC-MS/MS" document and lack of documentation revealed the laboratory failed to: a) document the names and serial numbers for three of three analyzers (Serial Number: SG1325A204, Serial Number: SG1709D003, Serial Number: SG1606D002) utilized for validation testing; b) identify Accuracy, Precision, Analytical sensitivity, Analytical specificity to include interfering substances, Reportable range of test results for the test system, Reference intervals (normal values), and any other performance characteristics required for adequate test performance for three of three analyzers (Serial Number: SG1325A204, Serial Number: SG1709D003, Serial Number: SG1606D002); c) provide documentation of instrument raw data validation runs for three of three analyzers (Serial Number: SG1325A204, Serial Number: SG1709D003, Serial Number: SG1606D002). 4. Review of laboratory documentation revealed 341,586 patient tests were performed for HuMap testing on one Agilent Technologies 6460 Triple Quad LC/MS analyzer, Serial Number: SG1325A204 and two Agilent Technologies 6495 Triple Quad LC/MS analyzers, Serial Numbers: SG1709D003 and SG1606D002 from 06/2022 to 11/08/2024. 5. On 11/08/2024, at 12: 41 p.m., the TS stated the validation documents for three of three analyzers (Serial Number: SG1325A204, Serial Number: SG1709D003, Serial Number: SG1606D002) for the HuMap assay were not on file for surveyor review.
D6168	TESTING PERSONNEL

	CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and interview with general supervisor #1; the laboratory failed to ensure 1 of 73 testing personnel (TP) were qualified for high complexity laboratory developed testing. See D6171.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with general supervisor (GS) #1; the laboratory failed to ensure 1 of 73 testing personnel (TP) were qualified for high complexity laboratory developed testing. Findings include: 1. Review of personnel educational documentation revealed 1 of 73 TP (TP #57) failed to meet the education requirements to qualify as a high complexity TP. 2. On survey date 11/08/2024, at 2:26 pm, GS #1 confirmed TP #57 was not qualified for high complexity laboratory developed testing.