Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2116823	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madison Core Laboratories	2705 Artie St Sw Bldg 400 Suite 25, Huntsville, AL	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of temperature records, the operator's manual, and an interview with the Technical Consultant and Quality Specialist, the laboratory failed to define acceptable criteria for humidity, consistent with the manufacturer's instructions for the operation of the Carolina Liquid Chemistries (CLC) 800. This was noted from January 2020 to current survey (03/10/2022). The findings include: 1. A review of temperature records revealed the following: a) 2020 room temperature/humidity log did not have a documented acceptable range. Nine out of twelve months reviewed had humidity below 40% for multiple days. b) 2021 room temperature/humidity log acceptable range was documented as 20 - 75%. Nine out of twelve months reviewed had humidity below 40% for multiple days. c) 2022 room temperature/humidity log acceptable range was documented as 15- 65%. Two out of two months reviewed had humidity below 40% for multiple days. 2. A review of the Operator's Manual for the CLC 800 revealed: "Relative humidity: 40% - 85". 3. During an interview on 03/10 /2022 at 2:00 PM, the Technical Consultant and Quality Specialist confirmed the acceptable range for the relative humidity in the CLC Room (accessioning room) should have been 40 - 85%. Also, they confirmed that on multiple days, the staff documented relative humidity below 40% for the room that houses the CLC 800.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of adulterants (specific gravity (SG), pH, and creatinine) quality control, package inserts, quality control procedure, and an interview with the Technical Consultant, the laboratory failed to perform quality control at the frequency specified by the manufacturer for creatinine and provide an Individualized Quality Control Plan (IQCP) for SG and pH. This was noted from previous survey (05/22 /2019) to current survey (03/10/2022). The findings include: 1. A review of adulterants quality control revealed the following: a) Specific gravity had one level of control run each day of patient testing from July 2019 to June 2020. Starting in July 2020, each week, one lower and one upper level control was performed on specific gravity. The remaining days of the week that patient testing was performed, only one level of control was performed. b) pH had one level of control run each day of patient testing from July 2019 to June 2020. Starting in July 2020, each week, one lower and on upper level control was performed on pH. The remaining days of the week that patient testing was performed only one level of control was performed. c) Creatinine had one level of control run each day of patient testing from July 2019 to June 2020. Starting in July 2020, each week, one lower and on upper level control was performed on creatinine. The remaining days of the week that patient testing was performed only one level of control was performed. 2. A review of adulterants reagents package inserts revealed the following: a) DRI Gravity-Detect Test (specific gravity) - "All quality control requirements should be performed in conformance with local, state and /or federal regulations or accreditation requirements." b) DRI pH-Detect Test (pH) - "Good laboratory practice suggests the use of control specimens to validate the calibration and the ensure proper assay performance." c) Creatinine Liquid Reagent Assay - "These controls should be run at least with every working shift in which Creatinine assays are performed." 3. A review of the laboratory's Quality Control Plan revealed under Quality Control Frequency "...Each week one lower and one upper-level control are used to determine acceptability. For daily control purposes, ... only the lower level is used for adulterants..." 4. During an interview on 03/10/2022 at 12: 00 PM , the Technical Consultant stated the IQCP for SG and pH could not be located and confirmed the package insert for Creatinine would not allow an IQCP.