Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2097667	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Madison Core Laboratories	2705 Artie Street Sw, Suite 30, Building 400, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of Sysmex CA-600 records and interviews with Testing Personnel (TP) #2, and the Technical Consultant (TC), the surveyor determined the laboratory failed to utilize the correct samples to determine the normal patient mean for the Innovin (Protime) reagent, and failed to verify the INR (International Normalized Ratio) generated by the analyzer until the day of the survey. This affected one of one lot numbers of Innovin reagent in use for seven months since 2/6/2020. The findings include: 1. A review of the calibration information on the Sysmex CA-600 (used for Protime testing) revealed the laboratory has used Innovin Lot # 549720 for PT/INR testing since 2/6/2020. 2. On 9/10/2020 at 8:55 AM when the surveyor requested the validation information for Lot # 549720, the TC stated all he had were the instrument printouts of the Level 1 and Level 3 Quality Control (QC) run ten times each on 2/6 /2020 by TP #2. 3. In an interview on 9/10/2020 at 9:00 AM, the surveyor asked TP #2 how she determined the normal patient mean (NPM) for new lot numbers of Innovin reagent. TP #2 stated she had established the mean using the normal Level 1 QC. The surveyor explained plasma from normal patients must be used to calculate the NPM; the plasma may be acquired commercially or obtained from health donors. TP #2 stated she had not known that was required. 4 The surveyor then asked the Technical Consultant if the laboratory had verified (via manual calculations) the INR generated by the Sysmex CA-600. The TC stated he had not realized this was required; thus the above noted deficiencies were confirmed. .

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance records and an interview with the Technical Consultant (TC), the laboratory failed to ensure corrective actions were implemented and documented when weekly cultures of samples from the deionized water system (used for the Chemistry and Immunochemistry analyzers) were positive for bacterial growth. This was noted on five out of nine positive cultures reviewed during the survey. The findings include: 1. During the initial tour on 9/9/2020 between 9-9:30 AM, the surveyor noted the Cobas c501 (for Chemistry and toxicology testing) and the Cobas e601 (used for immunochemistry testing) received the water supply from a Medica deionized water system. 2. A review of the 2018-2020 quality assurance records on 9/10/2020 revealed the laboratory routinely sent out water from the deionized system for weekly cultures. The surveyor noted nine times when the water cultures were positive for bacterial growth, however on five days (1/17/2018, 12/10 /2018, 7/6/2019, 8/23/2019, and 8/28/2019), there was no corrective action documented. 3. During an interview on 9/10/2020 at 2:15 PM, the surveyor reviewed the above noted findings with the TC, who confirmed the above noted findings. The surveyor also explained laboratory needed to ensure testing personnel understood what action should be taken whenever there was a positive water culture. SURVEYOR #32558 Licensure and Certification Surveyor