Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2116823	05/22/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a lack of 2018-2019 proficiency testing, and an interview with the Technical Supervisor (TS) #1, the surveyor determined the laboratory failed to enroll in proficiency testing (PT) with a CMS-approved PT provider for regulated tests in the Microbiology specialties since patient testing began in December 2017. The findings include: 1. During the entrance tour of the laboratory on 5/22/2019 at approximately 9: 00 AM, TS #1 explained the laboratory had implemented major changes in the scope of testing due to a change in ownership after the initial survey on 7/5/2017. The laboratory name had also changed since the previous survey. TS #1 listed the following on the new laboratory test menu: Urine Toxicology Screening on the CLC (Carolina Liquid Chemistries Corporation)-800 (Nine drugs plus urine Creatinine) Confirmatory Drug Testing on the Agilent Technologies 6420 Triple Quad LC/MS (Liquid Chromatography/Mass Spectrometry) Molecular (PCR or Polymerase Chain Reaction) Testing for infectious organisms on two QuantStudio 12K Flex Systems and the Autogenomics Infinity HTS system 2. In an interview with TS #1 on 5/22 /2019 at 11:00 AM, the surveyor asked whether testing of patients was interrupted due to the change in the laboratory ownership. TS #1 explained no testing was performed August to November 2017. In December 2017 the laboratory began performing PCR

	Testing for Respiratory Pathogens on the Autogenomics Infinity HTS. After the new ownership change in May 2018, the laboratory resumed toxicology testing; additional PCR testing for Bacterial Vaginosis and Candidal Vaginitis using the Autogenomics Infinity HTS began in August 2018. In May and August 2018 the laboratory also validated two QuantStudio 12K Flex Systems which were used for PCR detection of pathogens in Wound, Urine and STD (Sexually Transmitted Diseases) patient specimens. 3. On 5/22/2019 at 1:10 PM the surveyor requested proficiency testing records for the above test menu. TS #1 explained they had discontinued enrollment in PT after the termination of the moderate-complexity testing in August 2017, and they had not enrolled in 2018 or 2019 after implementation of the new test menu. Instead, TS #1 provided the Testing Personnel with "spiked samples" for Toxicology and Molecular (PCR) Diagnostic testing in April 2019. TS #1 stated the Testing Personnel also performed the blind testing in October 2018, however the laboratory had no documentation of the results due to "power surge damage to a computer during a tornado" in early May 2019. The TS assessed accuracy of the CLC-800 by comparing the patient results with the results obtained on the Agilent LC/MS system, and tabulating the statistical accuracy. 4. As the interview continued at 1:15 PM, the surveyor explained CLIA required PT enrollment for the regulated Microbiology specialties, if PT was available. The surveyor then reviewed the CMS approved PT providers, and which one had proficiency testing available for the laboratory's Molecular (PCR) Diagnostic testing. .
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 a lack of 2018 accuracy verification documentation, no accuracy verification procedures, and an interview with the Technical Supervisor (TS) #1, the surveyor determined the laboratory failed to either enroll in proficiency testing (PT) with a CMS-approved PT provider or perform any accuracy verification comparing the laboratory's results with an outside laboratory at least twice a year since patient testing began in December 2017. The findings include: 1. During the entrance tour of the laboratory on 5/22/2019 at approximately 9:00 AM, TS #1 explained the laboratory had implemented major changes in the scope of testing due to a change in ownership after the initial survey on 7/5/2017. The laboratory name had also changed since the previous survey. TS #1 listed the following on the new laboratory test menu: Urine Toxicology Screening on the CLC (Carolina Liquid Chemistries Corporation)-800 (Nine drugs plus urine Creatinine) Confirmatory Drug Testing on the Agilent Technologies 6420 Triple Quad LC/MS (Liquid Chromatography/Mass Spectrometry) Molecular (PCR or Polymerase Chain Reaction) Testing for infectious organisms on two QuantStudio 12K Flex Systems and the Autogenomics Infinity HTS system 2. In an interview with TS #1 on 5/22/2019 at 11:00 AM, the surveyor asked whether testing of patients was interrupted due to a change in the laboratory ownership. TS #1 explained no testing was performed August to November 2017. In December 2017 the laboratory began performing PCR Testing for Respiratory Pathogens on the Autogenomics Infinity HTS. After the new ownership change in May 2018, the laboratory resumed Urine Toxicology testing; additional PCR testing for Bacterial Vaginosis and Candidal Vaginitis using the Autogenomics Infinity HTS began in August 2018. In May and August 2018 two QuantStudio 12K Flex Systems were

	validated, and in use for patient testing for PCR detection of pathogens in Wound, Urine and STD (Sexually Transmitted Diseases) patient specimens. 3. On 5/22/2019 at 1:10 PM the surveyor requested proficiency testing records for the above test menu. TS #1 explained they had discontinued enrollment in PT after the termination of the moderate-complexity testing in August 2017, and they had not enrolled in 2018 or 2019 after implementation of the new test menu. Instead, TS #1 provided the Testing Personnel with "spiked samples" for Toxicology and Molecular (PCR) Diagnostic testing in April 2019. The TS stated the Testing Personnel also performed the blind testing in October 2018, however the laboratory had no documentation of the results due to "power surge damage to a computer during a tornado" in early May 2019. The TS assessed accuracy of the CLC-800 by comparing the patient results with the results obtained on the Agilent LC/MS system, and tabulating the statistical accuracy. 4. As the interview continued at 1:15 PM, the surveyor asked if the laboratory had procedures for performance of accuracy verification with criteria for acceptability, and TS #1 answered, "Not really". The surveyor then explained the laboratory must have a method of verifying the accuracy of non-regulated Urine Toxicology testing at least every six months (or twice a year), however the laboratory provided no 2018 documentation. Of further concern was the fact that the laboratory had no mechanism of verifying the accuracy of their results via an outside laboratory or thru enrollment with an approved PT provider. Only results for two internally-prepared spiked samples run in April 2019 were available for review. The laboratory failed to provide any 2018 accuracy verification records. 5. The surveyor further explained CLIA required PT enrollment for regulated Microbiology specialties, if PT was available. (Refer to D2000.)
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the maintenance procedures in the electronic Operator's Manual for the two QuantStudio 12K Flex Systems (which use PCR [Polymerase Chain Reaction] to identify pathogenic organisms), a lack of laboratory maintenance records, and interviews with the Technical Supervisor (TS) #1 and the Manager of Quality and Training, the surveyor determined the laboratory failed to perform and document the weekly, monthly and annual maintenance with the frequency required by the manufacturer since January 2018. The findings include: 1. A review of the maintenance records for the two QuantStudio 12K Flex Systems revealed only documentation of annual calibrations performed on 5/3/2019 for Quant #406; the calibration for the newer Quant #448 was dated 4/29/2019. The Quant #406 was in use for infectious disease testing since May 2018 when the laboratory ownership changed, per the TS #1 in an interview on 5/22/2019 at 11:00 AM. Quant #448 was validated and in use in August 2018. 2. A review of an electronic copy of the QuantStudio 12K Flex Operator's Manual in section 2, page 36, "Recommended calibration and maintenance", revealed the following: "...Weekly ...Power off the computer that controls the QuantStudio 12K Flex System, then after 30 seconds power on the computer. Clean the surface ... with a lint-free cloth. Perform ... Instrument self-test" "Monthly Perform a background calibration. Run disk cleanup and disk defragmentation." "Annually Perform a regions of interest (ROI),...a

	background, ...a uniformity, ...a dye, [and] ...a normalization calibration. Perform an instrument verification run." [There was no documentation the annual calibrations were performed in 2018 for Quant #406.] 3. During a review of the above electronic information and an interview on 5/22/2019 at approximately 4:15 PM, TS #1 and the Manager of Quality and Training confirmed the laboratory had not documented performance of the above maintenance procedures. .
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 documentation and interviews with the Technical Supervisor (TS) #1, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory implemented documentation of monthly quality assurance activities in January 2019, however the reviews in 2018 and 2019 were inadequate to discover and correct problems in the following areas: A.) 2018-2019 Enrollment in proficiency testing (PT) with a CMS-approved PT provider for regulated tests in the Specialty of Microbiology; PT enrollment or implementation of a mechanism comparing the laboratory's results with an outside laboratory at least twice a year to ensure verification of the accuracy of test results for non-regulated moderate and high-complexity Urine Toxicology testing (Refer to D2000 and D5217.) B.) Perform and document the QuantStudio 12K Flex System weekly, monthly and annual maintenance with the frequency required by the manufacturer (2018 and 2019) (Refer to D5429.) C.) Review of environmental logs to ensure acceptable room temperature ranges were specified as determined by review of the manufacturer's operating requirements for the equipment in use (2018 and 2019) D.) Review of 2018 validation records to ensure the Laboratory Director and Technical Supervisor dated their review/approval of three new procedures, thus ensuring there was documentation the approval was made before the new systems were utilized for patient testing. 2. During the exit summation on 5/22/2019 at 5:00 PM, these concerns were reviewed and discussed with TS #1. SURVEYOR ID# 32558 Licensure and Certification Surveyor