Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2116823	12/22/2022
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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of the CASPER report #155, and the API (American Proficiency Institute) proficiency testing evaluations, the laboratory failed to successfully participate in Toxicology testing for Digoxin (therapeutic drug monitoring) for two of three consecutive testing events, Event #1 and Event #3, 2022. These failures resulted in an initial unsuccessful proficiency testing failure. The findings include: Refer to D2109.
D2109	TOXICOLOGY CFR(s): 493.845(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of the CASPER report #155, and the API (American Proficiency Institute) proficiency testing evaluations, the laboratory failed to perform satisfactorily in Toxicology testing for Digoxin for two of three consecutive testing events, Event #1 and Event #3, 2022. The findings include: 1. A review of the CASPER report revealed the laboratory scored the following: a) Event #1, 2022 Digoxin 60 % b) Event #3, 2022 Digoxin 60 % 2. A review of the API proficiency testing evaluations confirmed the above mentioned scores.