Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2097667	05/18/2020
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
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 API (American Proficiency Institute) proficiency testing evaluations and CMS (Centers for Medicare and Medicaid) CASPER reports (#153 / #155), the surveyor determined the laboratory failed to successfully participate in proficiency testing for two consecutive testing events for the WBC (White Blood Cell) Differential. These failures resulted in an initial unsuccessful proficiency testing participation for the laboratory. The findings include: 1. The laboratory scored twelve percent (12 %) for the WBC Differential [zero percent for the Basophils, Eosinophils, Monocytes and Neutrophils; and sixty percent for Lymphocytes] for the 2019

	Hematology testing event #3. The laboratory scored 28 % for the WBC Differential [zero percent for the Basophils, Eosinophils and Neutrophils; and 60 % for the Lymphocytes] for event #1, 2020. 2. These two consecutive failures of the WBC Differential for Event #3, 2019 and Event #1 of 2020 resulted in an initial unsuccessful proficiency testing participation. 3. The surveyor confirmed the above noted findings by review of the CASPER reports and the API proficiency testing records for 2017 - 2020 (first event).
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing evaluations and CMS (Centers for Medicare and Medicaid) CASPER reports (#153 / #155), the surveyor determined the laboratory failed to perform satisfactorily in proficiency testing for the WBC (White Blood Cell) Differential for Event #3, 2019 and Event #1, 2020, two consecutive testing events. These failures resulted in an initial unsuccessful proficiency testing participation for the laboratory. The findings include: Refer to D2016.