Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405516	03/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Madison Healthcare Services	900 2nd Ave, Madison, MN	

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 Center for Medicare and Medicaid Services reports and American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in proficiency testing (PT) in 2019 for Compatibility Testing under the specialty of Immunohematology. Findings include: 1. The CASPER Report 0155D, reviewed on March 9,2019, indicated the the laboratory failed to successfully participate in Compatibility Testing in 2019. Unsatisfactory PT performance in Compatibility Testing was obtained in the following events. -2019 3rd

	event 60% -2019 1st event 60% 2. The CASPER Report 0155D indicated the laboratory failed to obtain a Compatibility Testing PT score of at least 100 percent in two out of three consecutive testing events in 2019. See D2173 and D2181
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score in Compatibility Testing of at least 100 percent which resulted in unsatisfactory performance. Unsatisfactory PT performance of Compatibility Testing was obtained in the following events. -2019 1st event 60% -2019 3rd event 60%
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on proficiency testing scores from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for Compatibility Testing in two out of three consecutive testing events, constituting unsuccessful participation for the analyte. API results indicated the laboratory had unsatisfactory performance for Compatibility Testing in two out of three consecutive events, leading to unsuccessful participation. Unsatisfactory PT performance of Compatibility Testing was obtained in the following events. -2019 1st event 60% -2019 3rd event 60%