

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405516	(X3) Date Survey Completed 06/12/2025
Name of Provider or Supplier Madison Healthcare Services	Street Address, City, State 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
D0000	The Madison Healthcare Services laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the proficiency testing desk review survey performed on June 12, 2025. The following condition-level deficiencies were cited: 493.803 Successful Participation The following standard-level deficiencies were cited: 493.863 Compatibility testing . .
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 review of proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the

	laboratory failed to successfully participate in Compatibility Testing PT under specialty of Immunohematology in 2024 and 2025. Findings are as follows: 1. The CMS CASPER Report 0155D and the API 2024 Immunohematology/Immunology - 2nd Event Performance Summary and Comparative Evaluation and the API 2025 Immunohematology/Immunology - 1st Event Performance Summary and Comparative Evaluation were reviewed on June 12, 2025. 2. The reports indicated the laboratory failed to achieve satisfactory performance for Compatibility Testing in two of three consecutive testing events from 2024 and 2025, resulting in unsuccessful performance of the analyte (see D2181). .
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) (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 (PT) 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 in 2024 and 2025, constituting unsuccessful participation for the analyte. Findings are as follows: 1. API Performance Summary and Comparative Evaluation PT reports from the 2024 Immunohematology/Immunology 2nd Event and the 2025 Immunohematology /Immunology 1st Event were reviewed on June 16, 2025. 2. The reports indicated the laboratory had unsatisfactory performance for Compatibility Testing in two out of three consecutive events, leading to unsuccessful participation. See below. Unsatisfactory Compatibility Testing PT Events: Event Score 2024 2nd Event 80% 2025 1st Event 80% .