Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0711692	01/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
David R Mandel Md Inc	6551 Wilson Mills Road, Suite 106, Mayfield Village, OH	

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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 record review and an interview with the General Supervisor (GS), the laboratory failed to attain a proficiency testing (PT) score of at least 80 percent of acceptable responses for the analyte Vitamin D (VitD) in the first testing event and for the analyte Complement (C3) in the third testing event of 2020 in the subspecialty of General Immunology. All patients tested for VitD between the first and second testing events of 2020 and for C3 between the third testing event of 2020 and the first testing event of 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Quality Assessment" policy and procedure, provided on the date of the inspection and approved by the Laboratory Director via signature and date on 03/15/2011, found a section titled "Proficiency Testing" that revealed the following statement: "2. Unsatisfactory performance: a score of less than 80% for an analyte" 2. Review of the laboratory's 2020 and 2021 American Proficiency Institute (API) PT documentation, provided on the date of the inspection, revealed an analyte testing score of 50% for VitD in the first testing event and 60% for C3 in the third testing event of 2020. 3. The GS confirmed the laboratory did not achieve a PT analyte testing score of at least an 80% for VitD in the first testing event and for C3 in the third testing event of 2020. The interview occurred on 01/13/2022 at 10:15 AM.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 record review and an interview with the General Supervisor (GS), the laboratory failed to attain a proficiency testing (PT) score of at least 80% (percent) of acceptable responses for the analyte blood urea nitrogen (BUN) in the first testing event of 2021 in the subspecialty of Routine Chemistry. All patients tested for BUN between the first and second testing events of 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Quality Assessment" policy and procedure, provided on the date of the inspection and approved by the Laboratory Director via signature and date on 03/15/2011, found a section titled "Proficiency Testing" that revealed the following statement: "2. Unsatisfactory performance: a score of less than 80% for an analyte" 2. Review of the laboratory's 2020 and 2021 American Proficiency Institute (API) PT documentation, provided on the date of the inspection, revealed an analyte testing score of 0% for BUN in the first testing event of 2021. 3. The GS confirmed the laboratory did not achieve a PT analyte testing score of at least an 80% for BUN in the first testing event of 2021 due to clerical errors. The interview occurred on 01/13/2022 at 10:15 AM.
D2121	HEMATOLOGY CFR(s): 493.851(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 record review and an interview with the General Supervisor (GS), the laboratory failed to attain a proficiency testing (PT) score of at least 80 percent of acceptable responses for the analyte mean corpuscular hemoglobin (MCH) in the second testing event of 2021 in the specialty of Hematology. All patients tested for MCH between the second and third testing event of 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Quality Assessment" policy and procedure, provided on the date of the inspection and approved by the Laboratory Director via signature and date on 03/15/2011, found a section titled "Proficiency Testing" that revealed the following statement: "2. Unsatisfactory performance: a score of less than 80% for an analyte" 2. Review of the laboratory's 2020 and 2021 American Proficiency Institute (API) PT documentation, provided on the date of the inspection, revealed an analyte testing score of 40% for MCH in the second testing event of 2021. 3. The GS confirmed the laboratory did not achieve a PT analyte testing score of at least an 80% for MCH in the second testing event of 2021. The interview occurred on 01/13/2022 at 10:15 AM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to consistently include the correct address of the laboratory location in which the laboratory testing was conducted on the final test report. This deficient practice had the potential to affect all patients tested at this laboratory location under the sub-specialties of General Immunology, Routine Chemistry and Hematology. Findings Include: 1. Review of 36 out of 36 of the laboratory's final patient test reports revealed six final test reports that did not indicate the correct address of the laboratory location in which laboratory testing was conducted. The six final test reports indicated the address of a second office location that has since closed on 01/01 /2022. 2. The GS confirmed the laboratory did not consistently indicate the correct address of the laboratory location in which the laboratory testing was conducted on the final patient test report. The interview occurred on 01/13/2022 at 10:45 AM.