Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0642547	04/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mn Clinical Laboratory	1330 Arrow Hwy, La Verne, CA	

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
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the AAB-Medical Laboratory Evaluation (AAB) and the College of American Pathologists (CAP) Proficiency Testing (PT) records and interview with the laboratory technical supervisor (TS) and laboratory director (LD); it was determined that the laboratory failed to attain a score of least 80 percent of acceptable responses for Rubella and Anti-HIV. The findings included: 1. Based on review of PT records for the third event of 2021 (Q3-2021) AAB reported an unsatisfactory score of 60% for Rubella PT testing. 2. Based on review of PT records for Q3-2021, CAP reported an unsatisfactory score of 20% for Anti-HIV testing. 3. Based on the laboratory's testing declaration at the time of the survey on April 28, 2023, the laboratory reported approximately 51,936 General Immunology tests results which include both Rubella and Anti-HIV analytes during the time the laboratory had unsatisfactory PT testing scores. 4. The TS affirmed that the laboratory received the above unsatisfactory General Immunology Rubella and HIV analytes PT scores
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 review of the AAB-Medical Laboratory Evaluation (AAB) proficiency

	testing (PT) records, five (5) randomly chosen patient results, and interview with the technical supervisor; it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Routine Chemistry analyte CK, Total. The finding included: 1. Based on review of PT records for the Q3-2022, AAB reported an unsatisfactory score report of 60% for CK, Total analyte. 2. Based on the laboratory testing declaration submitted at the time of the survey on 4/28/2023, the laboratory analyzed and reported approximately 1,141.062 Routine Chemistry tests including CK, Total during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed on 4/28/2023 at approximately 11:45 a.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory's technical supervisor and testing personnel (TP) on April 28, 2023 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using automated and manual methods for preparation of the master-mixes, controls and reagents, and addition of template. 2. During the laboratory tour on April 28, 2023, at approximately 3:30 p.m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same room/area without unidirectional flow. 3. The TS and TP confirmed by interview that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 3,748 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's proficiency testing (PT) records for the years of 2021, 2022, 2023 and interview with the technical supervisor (TS) on April 28, 2023 the laboratory failed to retain its PT test records for two PT events in 2021. The findings include: 1. The laboratory failed to locate PT laboratory data and testing results for Rubella and anti-HIV PT Q3-2021 provided by AAB-Medical Laboratory Evaluation and the College of American Pathologists respectively, 2. The laboratory TS affirmed on April 28, 2023, at approximately 2:30 p.m. that the

	laboratory did not keep Q3-2021 PT results documentation for Rubella and Anti-HIV testing results. 3. The laboratory's testing declaration form, signed by the laboratory Director on 4/28/2023, stated that the laboratory performs 51,936 General Immunology samples annually including the analytes mentioned in 2.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyor's direct observations of the laboratory's SARS-CoV-2 PCR testing processes and interview with the laboratory's director, technical supervisor, and testing personnel on April 28,2023; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the PCR testing performed. Findings include: See D3005.