Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0642547	03/05/2021
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
D2020	BACTERIOLOGY CFR(s): 493.823(a) 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 American Association of Bioanalysts (AAB) proficiency testing (PT) results reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent was unsatisfactory performance. The findings included: a. The laboratory performed bacteriology and report non-growth and groth of organisms with culture identification. b. The laboratory enrolled its proficiency testing program with AAB. c. The laboratory attained an overall testing score of 75% in Culture Identification (ID) for the Q1 2020 Bacteriology PT event, which was unsatisfactory performance. d. The laboratory performed bacteriology in approximately 3711 patient samples monthly. e. The laboratory personnel affirmed (3/5/2021 @ 2:45 PM) that the laboratory attained an overall testing score of 75% for Culture Identification in the Q1 2020 Bacteriology PT event, which was unsatisfactory performance.
D2109	TOXICOLOGY CFR(s): 493.845(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 American Association of Bioanalysts (AAB) proficiency testing (PT) results reports, and interview with the laboratory testing personnel, it was

	determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Toxicology PT testing event is unsatisfactory analyte performance. The findings included: a. The laboratory performed Toxicology including but not limited to Phenobarbital. b. The laboratory enrolled its proficiency testing program with AAB for the Toxicology testings.. c. The laboratory attained a score of 60% for Phenbarbital in the Q1 2019 Toxicology PT event, which was unsatisfactory performance. d. The laboratory performed Phenobarbital in approximately 9 patient samples monthly. e. The laboratory personnel affirmed (3/5 /2021 @ 2:45 PM) that the laboratory attained a score of 60% for Phenobarbital in the Q1 2019 Toxicology PT event, which was unsatisfactory performance.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's daily quality control (QC) records and Levy Jennings (LJ) charts, and interview with the laboratory testing personnel, it was determined that the laboratory failed to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance, and failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. The findings included: a. The laboratory use Roche Instrument to perform and report the routine chemistry tests including but not limited to Alfa Feto Protein (AFP) and Alk. Phosphatase (ALP). b. The laboratory purchased assayed commercial QC materials and elected to use the assayed mean and standard deviation (SD) data published by the manufacturer instruction (MI), after the laboratory had verified the new batch of the MI concurrent with the laboratory's current QC results in daily run. c. A LJ chart provides cumulative quality control data information for trending or shifting in serials QC run. d. The laboratory used three levels of BioRad QC materials, Q1, Q2, and Q3, for AFP lot # 85231, 85232, and 85233, for ALP lot # 45811, 48512, and 45813. e. Review a LJ chart for AFP from 12 /01/2020 thru 01/03/2021, about 30 run data, had indicated calculated Q1 mean 29.42 (23.6 - 35.2) vs set mean 32.8 (25.8 - 39.8) ; calculated Q2 mean 116.5 (96.5 - 135.5) vs set mean 128 (102.4 - 153.6) , and calculate Q3 mean 239.7 (197.7 - 281.7) vs. set mean of 263 (211 - 315), which indicated all three levels showing negative shift from their mean setting. f. Review a LJ chart for ALP from 12/01/2020 thru 01/03/2021, about 30 run data, had indicated Q1 with calculated mean 28.9 (24.9 - 32.9), in a negative bias/shift vs set mean of 33.9 (26.7 - 41.0) , and Q3 calculated mean 293 (257 - 329) Q3 vs set 279 (243 - 315) data, which indicated a positive bias/shift from

	their mean setting. g. The laboratory failed to monitor and take actions for this bias shifting QC values. h. The laboratory personnel affirmed (3/5/2021 @ 1:50 PM) that the laboratory failed to monitor and take actions for this negative bias shifting.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) results reports, and interview with the laboratory testing personnel, it was determined that the laboratory director who is failed to be responsible for the overall operation and administration of the laboratory, including but are not limited to ensure that the proficiency testing samples were tested as required and be satifactory for all events. The findings included: a. The laboratory performed multiple subspecialties and spectialties tests including, but are not limited to the following: Culture Identification and Toxicology. b. The laboratory enrolled its proficiency testing programs with AAB for the Bacteriiology and Toxicology tests.. c. The laboratory attained an overall testing score of 75% for Culture Identification in the Q1 2020 Bacteriology PT event, which was unsatisfactory performance, see D-2020. c. The laboratory attained a score of 60% for Phenbarbital in the Q1 2019 Toxicology PT event, which was unsatisfactory performance see D-2109.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's daily quality control (QC) records and Levy Jennings (LJ) charts, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to identify failures in quality as they occur. The findings included: a. The laboratory use Roche Instrument to perform and report the routine chemistry tests results including but not limited to Alfa Feto Protein (AFP) and Alk. Phosphatase (ALP). b. The laboratory purchased assayed commercial QC materials and elected to use the assayed mean and standard deviation (SD) data published by the manufacturer instruction (MI), after the laboratory had verified the new batch of the MI mean values concurrent with the laboratory's current QC results in daily run. c. Two LJ charts, AFP and ALP between

	12/02/20 thru 01/03/2021 were found negative bias shifting, and the laboratory failed to take actions, see D-5441