Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0544586	05/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Elayne K Garber Md A Medical Corp	8631 W 3rd St Ste 700e, Los Angeles, 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
D2122	HEMATOLOGY CFR(s): 493.851(b) (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 the surveyor's review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory director (LD); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the first event of 2025 (Q1-2025) which was unsatisfactory performance for the testing event. The findings include: 1. The API proficiency program gave an unsatisfactory score of 40% for the Hematocrit and Red Blood Cell (RBC) analytes for Q1-2025. 2. The LD affirmed by interview on May 19, 2025, at approximately 10:30 a.m. that the laboratory received the unsatisfactory score as mentioned in statement #1. 3. The reliability and quality of Hematology results reported could not be assured when the laboratory failed to attain overall scores of at least 80% in proficiency testing. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported 8,900 tests in Hematology annually including the time when unsatisfactory scores were obtained.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for

	the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the lack of a complete laboratory verification of performance specifications for Hematology, proficiency testing records, and an interview with the laboratory director (LD) on May 19, 2025, it was determined that the laboratory failed to provide a complete documentation for performance specifications when a new instrument replacement was obtained. The findings include: 1. A review of the proficiency testing records showed that the laboratory failed the first testing event of 2025, resulting to an unsatisfactory score. The Mindray BC 1300 instrument, used for Complete Blood Count (CBC) testing, was replaced with another of the same make and model after the scores were obtained. 2. The surveyor ' s review of the laboratory's performance specifications documentation indicated that due to the unexpected instrument issue, the method correlation was modified and tested by an external laboratory but a Sysmex instrument was utilized instead. Consequently, due to the differing methodologies, this method correlation was deemed invalid. Therefore, the quality and reliability of the reported test results cannot be assured. 3. The LD stated on an interview on May 19, 2025, at approximately 10:35 a.m., that the previous instrument was considered irreparable and unfit for method correlation, as mentioned in statement #1. Rather than conducting a full performance specifications, an alternative method was performed as mentioned in statement #2. 4. Based on the testing declaration submitted at the time of survey, the laboratory performed and reported approximately 8,900 tests for Hematology annually that included CBC.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of laboratory quality control (QC) documentation, surveyor's review of policy/procedure, patient records, and an interview with the laboratory director (LD), it was determined that the laboratory failed to document QC performed prior to patient testing for the years 2022, 2023, 2024, and 2025. The findings include: 1. The laboratory's policy/procedure was to perform QC for rheumatoid arthritis (RA) test prior to patient testing. However, documentation was consistent only until February 8, 2022. After this date, QC was recorded only when a new lot was used. 2. The laboratory failed to provide documentation of reviewed or performed QC results for acceptability on each day of testing prior to analyzing patients samples when patient records were reviewed for the years 2022, 2023, 2024 and 2025. 3. The LD affirmed in an interview on May 19, 2025, at approximately 11:00 a.m., that QC was performed but not documented prior to patient testing after initial run of each lot. 4. The reliability, accuracy, and quality of results reported could not be assured. According to the laboratory's estimated annual tests volumes, 100 tests were performed and reported for RA including the time when QC documentation was incomplete.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the deficiency found last survey on May 19, 2025, the laboratory director is herein cited for deficient practice in ensuring verification of performance specifications were valid prior to patient testing. See D5421.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the surveyor's review of the unsatisfactory proficiency testing score for the first event of 2025, the laboratory director is herein cited for failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2122.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the surveyor's findings on May 19, 2025, and the lack of quality control documentation, the laboratory director is herein cited for the deficient practice of failure to ensure quality control programs were followed to assure and monitor the quality of laboratory services provided, and to identify issues as it occurred. See D5481.