Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0544586	03/07/2022
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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director (LD); it was determined that the laboratory lacked an eye wash station and a fire extinguisher in the laboratory. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey March 7, 2022, at approximately 2:00 p.m. the surveyor observed that the laboratory lacked an eye wash station in the area where samples are processed, neither could the LD locate the fire extinguisher. 2. The LD affirmed the lack of an eye wash station and a fire extinguisher in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the LD on 2/27/2022, the laboratory processes and reports approximately 9,000 patients' samples annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory's policies and procedures, lack of documentation, and interview with the laboratory director (LD), it was determined that the laboratory

	failed to perform and document maintenance and calibration of the microscopes as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's policies and procedures indicated that annual maintenance and calibration according to manufacturer's requirements be performed on the microscopes used in the laboratory (Zeiss). 2. The LD confirmed on 3/7/2021 at approximately 1:45 p.m. that the laboratory failed to follow policies and procedures for maintenance and calibration of the microscope for the years 2020 and 2021. 3. According to the annual test volume declared by the laboratory LD the laboratory performs approximately 9,000 tests annually
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on the survey findings and deficiencies cited, the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory to ensure a safe environment in which personnel are protected from biohazardous materials. Findings include: See D3011
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency evaluation documentation for the testing personnel listed on the CMS-209 form and interview with the laboratory director (LD), it was determined that the laboratory's technical supervisor (same as LD) failed to evaluate and document direct observations and the performance of individuals responsible for routine patient testing performance, including patient preparation, if applicable, specimen handling, processing and testing. Findings include: 1. The laboratory did not have annual competency evaluation and documentation for the one testing person listed in the CMS 209 form for the years 2020 and 2021. 2. The LD affirmed on 3/7/2022 at approximately 2:30 p.m. having no records of documentation for competency of testing personnel for the years 2020 and 2021. 3. According to the annual test volume declared by the laboratory LD the laboratory performs approximately 9,000 tests annually