Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2003659	(X3) Date Survey Completed 03/31/2021
Name of Provider or Supplier E-Lab Of Las Vegas	Street Address, City, State 2950 S Rainbow Blvd Ste 260, Las Vegas, NV	

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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA initial survey conducted at your facility on March 31, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 a random audit of patient records, a review of the Quantstudio 7 Pro Maintenence Log, and an interview with the laboratory director, and with testing personnel #1 on the Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory failed to document the daily maintenance on all days of patient testing. Findings include: 1. A random audit of six patient test reports between the dates of January 4, 2021 and March 19, 2021 revealed that the daily maintenance was not documented for one of six days of patient testing. There was no documentation of the daily maintenance for the date of January 22, 2021. 2. A random audit of six patient test reports between the dates of January 4, 2021 and March 19, 2021 revealed that the daily maintenance was not documented accurately for the actual dates of patient testing due to the mislabeling of each day of the month for the maintenance log. The maintenance of the analyzer was not documented on February 15, 2021 and March 19, 2021. 3. A review of the daily maintenance log revealed that the log did not allocate spaces to document maintenance that corresponded to the dates between the 15th day of each month and the 21st day of each month. This was confirmed during an

	interview conducted on 3/31/21 at approximately 10:15 am with the laboratory director and testing personnel #1 listed on the CMS 209 form. The laboratory performs approximately 1000 Virology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 a review of the director approved quality assessment policy, monthly quality assessment documentation for the months of January, February and March 2021, and an interview with the laboratory director, the director failed to ensure that the established quality assessment program was maintained to ensure the quality of laboratory services and to identify failures in quality when they occur. Findings include: 1. The laboratory director failed to follow the director approved policy and procedure for quality assessment evaluation and documentation when evaluating the laboratory services provided by the laboratory for testing months January, February, and March 2021. 2. The laboratory director documented "N/A" for QA Plan, and Personnel Training covered in January, 2021, for Test Tracking and Communication covered in February 2021, and for Specimen Handling and Proficiency Testing covered in March 2021on the Quality Assurance Review Summary. This was confirmed during an interview conducted with the laboratory director on March 31, 2021 at approximately 10:30 am. The laboratory performs approximately 1000 Virology tests annually.