

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0705115	<b>(X3) Date Survey Completed</b>  08/30/2023
<b>Name of Provider or Supplier</b>  Robert E Anderson Md	<b>Street Address, City, State</b>  361 Hospital Rd Ste 333, Newport Beach, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of Bio-Rad Liquichek Immunoassay Plus Control levels 1, 2, and 3 stored in the freezer, review of manufacturer's instructions, documentation of freezer temperatures for August 2023, and interview with the technical consultant (TC) on August 30, 2023 at 08:45, the laboratory failed to follow the manufacturer's instructions for storage of quality control materials. Findings include: 1. Based on observation, the laboratory stored Bio-Rad Liquichek Immunoassay Plus Quality Control materials levels 1, 2, and 3 in a freezer not monitored with a thermometer but monitored with a screw cap micro-centrifuge container with solid contents to indicate that the freezer's contents remain frozen. 2. Review of the manufacturer's instructions for Bio-Rad Liquichek Immunoassay Plus Quality Control materials levels 1, 2, and 3 indicated that these quality control materials must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 3. The laboratory maintained no documentation to indicate that the Bio-Rad Liquichek Immunoassay Plus Quality Control materials levels 1, 2, and 3 had been stored at minus 20 - 70 degrees C. 4. According to laboratory documents, the Bio-Rad Liquichek Immunoassay Plus Quality Control materials levels 1, 2, and 3 were used by the laboratory to monitor the testing and</p>

reporting of 24,400 patient endocrinology test annually. 5. Interview with the TC on August 30, 2023 at 08:45 AM confirmed that the laboratory failed to properly monitor the freezer per the manufacturer's instructions.