

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2190510	<b>(X3) Date Survey Completed</b>  02/09/2022
<b>Name of Provider or Supplier</b>  Endeavor Dna, Inc	<b>Street Address, City, State</b>  6955 N Mesa St Suite 109, El Paso, TX	
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:</p> <p>I. Based on observation, review of manufacturer's instructions, temperature charts, pre-survey paperwork, and interview, the laboratory failed to store reagents according to the manufacturer's instructions for SARS-CoV-2 testing using the SalivaDirect real-time reverse transcription polymerase chain reaction (rRT-PCR) tested on the QuantStudio 5 for four of four months reviewed. Findings follow. A. Surveyor observed on February 9, 2022 at 1425 hours in the laboratory a frost-free freezer, "-20 ISO" refrigerator/freezer Insignia Model NS-RTM1OWH7. B. Freezer "-20 ISO" contained the following reagents with the manufacturer's storage requirements of -20 degrees Celsius: 1. A box of LUNA Universal Probe One-Step RT-qPCR Kit, Lot 10128913, expiration 12/2023 2. A box of LUNA Universal Probe One-Step RT-qPCR Kit, Lot 10122341, expiration 08/2023 3. A box of aliquots of American Bio Proteinase K lyophilized, 50mg/mL, no expiration date on the box. C. Review of the electronic record of the temperature chart for the "-20 ISO" refrigerator/freezer with temperatures taken every hour from 10/04/2021 - 02/07/2022 showed 4 temperatures within range out of 3,028 hourly readings over the course of 126 days. Most readings were between -11 - -19 degrees Celsius. D. Interview with the General Supervisor on February 9, 2022 at 1440 hours in the conference room confirmed the "-20 ISO" freezer temperatures were not maintained at -20 degrees Celsius. E. Review of the pre-</p>

survey paperwork showed an estimated testing volume of 2600 since May 3, 2022. II. Based on observation, review of the laboratory's policy and procedures, temperature charts, pre-survey paperwork, and interview, the laboratory failed to monitor and document the heat block used in the SARS-CoV-2 testing using the SalivaDirect real-time reverse transcription polymerase chain reaction (rRT-PCR) tested on the QuantStudio 5 for nine of nine months reviewed. Findings follow. A. Surveyor observed during a tour of the laboratory on February 9, 2022 at 1440 hours a Sci Gene Hybex Microsample Incubator (heat block). B. Review of the laboratory's policy and procedure titled SalivaDirect RT-PCR, effective March 31, 2021, under Prepare the Samples stated, "6. Heat inactivate proteinase K treated samples for 5 min at 95 degrees Celsius." C. Review of temperature charts in the laboratory showed no temperature recordings for the heat block. D. Interview with the General Supervisor on February 9, 2022 at 1440 hours in the laboratory confirmed the heat block temperatures were not documented. E. Review of the pre-survey paperwork showed an estimated testing volume of 2600 since May 3, 2022.