

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2025881	<b>(X3) Date Survey Completed</b> 09/22/2021
<b>Name of Provider or Supplier</b> Ent Associates Of Texas	<b>Street Address, City, State</b> 4401 Coit Rd #411, Frisco, 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>D0000</b>	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<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 direct observation, laboratory policy, and staff interview, the laboratory failed to ensure the proper storage conditions were maintained for Hema-Diff reagents for 12 of 12 months in 2020 and 9 of 9 months in 2021. Findings: 1. During a tour of</p>

the laboratory on 09/22/2021 at 9:20 am, the following were observed stored in the laboratory: Cabinet: 1 bottle of Hema-Diff #1 Fixative; lot # 124096; expiration date: 12/03/2022 1 bottle of Hema-Diff #2 Xantene; lot # 112996; expiration date: 06/30/2022 1 bottle of Hema-Diff #3 Thiazine; lot #113553; expiration date: 07/31/2022 Counter: 1 coplin jar Hema-Diff #1 Fixative; lot # 124096; expiration date: 12/03/2022 1 coplin jar Hema-Diff #2 Xantene; lot # 112996; expiration date: 06/30/2022 1 coplin jar Hema-Diff #3 Thiazine; lot #113553; expiration date: 07/31/2022 2. Review of laboratory policy titled "Diff-Quick Stain" revealed the following: "2. REAGENTS A. Hema Diff Fixative Solution I ... Storage: Store at room temperature (15-30C) ... B. Hema Diff Solution II ... Storage: Store at room temperature (15-30 degrees Centigrade) ... C. Hema Diff Solution III ... Storage: Store at room temperature (15-30 degrees Centigrade)" 3. During an interview on 09/22/2021 at 11:21 am, the laboratory director was asked if the temperature was monitored and documented in the laboratory and she stated "no because it is room temperature". She further stated that if there was no documentation in the binder then it was not performed, confirming the above findings. The laboratory failed to ensure the proper storage conditions were maintained for Hema-Diff reagents.