

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0671967	(X3) Date Survey Completed 12/02/2021
Name of Provider or Supplier Hayden H Franks Md Pa	Street Address, City, State 2011 Moores Ln, Texarkana, TX	
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	. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5413	<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 surveyor observation, review of laboratory environmental logs, and confirmed in interview, the laboratory failed to have a system in place to monitor the temperature for four of four reagents stored for histopathology. 1. During the tour of the facilities at 09:10 hours on 12/2/2021 the surveyor observed the following reagents in a flammable cabinet, in a closet, in a patient exam room. Eosin Y Hematoxylin 7211 Clear-Rite 3 PolarStat - Frozen Embedding Material 2. Based on review of laboratory environmental records the laboratory failed to have a temperature monitor in place for storage area for above reagents. 3. In an interview at 09:15 hours on 12/2/2021, in the patient exam room, the laboratory personnel confirmed that there was no temperature monitor in place for the storage of the above reagents. II. Based on review of the instrument instruction manual, laboratory environmental logs, and confirmed in interview, the laboratory failed to monitor humidity for the Leica CM1510S Cryostat, for eleven of eleven months reviewed. 1. Review of the instruction manual for the Leica CM1510S Cryostat (V1.4) Section 4. 'Setup', subsection 4.1 'Installation site requirements' lists the following humidity installations</p>

requirements that must be met. "relative humidity max. 60%" With an informational note stating, "high room temperature and excessive air humidity at the installation site affect the cooling capacity of the cryostat." 2. Based on review of the laboratory's 'Temperature Monitor Log - Refrigerator, Freezer, Cryostat' for January through November 2021 the laboratory failed to monitor the humidity for the Leica CM1510S Cryostat for eleven of the eleven months reviewed. 3. In an interview at 11:30 hours on 12/2/2021 with laboratory personnel at confirmed that the laboratory did not record the relative humidity for the Leica CM1510S Cryostat. .