

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0671967	(X3) Date Survey Completed 02/08/2023
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documents, patient test records, and confirmed in an interview, the laboratory failed to document Hematoxylin and Eosin (H&E) staining materials for intended reactivity each day of patient testing for 10 random patients reviewed in February, April, May, and June of 2022. The findings include: 1. In the laboratory walk-through on 2/8/2023 at 10:45 hours, the surveyor noted an H&E staining station used for patient testing. 2. Review of the laboratory policies and the laboratory vertical section specimen log did not include instructions or documentation of tissue stain acceptability for H&E. Surveyor queried if the information could be found in a separate place, and none was provided. 3. Review of random patient final reports in February, April, May, and June have the following 10 patients on days where there was no documented H&E stain acceptability: February 2022: patients Procedure Date: 2/14/2022 Path Number: 22-0543 Path Number: 22-0534 Path Number: 22-0551 Path Number: 22-0533 April 2022: 2 patients Procedure Date: 4/18/2022 Path Number: 22-1429 Path Number: 22-1430 May 2022: 2 patients Procedure Date: 5/23/2022 Path Number: 22-1998 Path Number: 22-1990 June 2022: 2 patients Procedure Date: 6/13/2022 Path Number: 22-2316 Path Number: 22-2320 4. In an interview on 2/8/2023 at 11:45 hours, in the office, the histo-tech confirmed that the H&E stain acceptability had not been documented for the above days where patients had been tested.</p>