

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2254711	(X3) Date Survey Completed 10/10/2022
Name of Provider or Supplier Amarillo Pathology Group Llp (Wolflin)	Street Address, City, State 4302 Wolflin Ave, Ste 200, Amarillo, 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 review of H&E quality control records, patient test records and interview of facility personnel, the laboratory failed to have documentation of the the negative and positive reactivity of quality control slides for Hematoxylin and Eosin (H &E) staining on each day of patient testing between September 19, 2022 and October 10, 2022. The findings included: 1. Documentation of H&E stain quality control records was requested but not provided. 2. Review of patient test records found 477 patient specimens tested with no documentation of quality control procedures. 3. Interview of the laboratory director conducted on October 10, 2022 at 11:48 AM confirmed that he had no records available for review of the intended reactivity of negative and positive control tissues each day of patient testing. He stated he was provided with a tissue control slide each day, but returned the documents to the laboratory performing the gross analysis and preparation of tissue specimens each day.</p>