

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0999016	(X3) Date Survey Completed 11/05/2020
Name of Provider or Supplier Cunningham Pathology	Street Address, City, State 2720 University Blvd, Birmingham, AL	
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 a review of quality control (QC) for Hematoxylin and Eosin (H&E) stain and an interview with Testing Personnel #3, the laboratory failed to retain documentation of H&E QC each day of patient testing. The findings include: 1. A review of quality control revealed that in 2019 and 2020 the quality of the stain was documented on the "Remote Frozen Section QA [Quality Assurance] Form" for each patient. 2. A review of the 2019 QA records revealed a total of 42 frozen cases were performed, however only 18 forms were retained in the laboratory. The laboratory was unable to specify the dates of the 24 other frozen cases in 2019, or whether H&E QC was performed and acceptable. 3. A review of the 2020 QA records revealed a total of 26 frozen cases (January - August), however only 22 forms were retained in the laboratory. The laboratory was unable to specify the dates of the other four frozen cases in 2020, or whether H&E QC was performed and acceptable. 4. During an interview on 11/05/2020 at 1:40 PM, Testing Personnel #3 confirmed the "Remote Frozen Section QA Form" should be retained in the laboratory to provide documentation of the daily quality control for the H&E stain. SURVEYOR ID #32558 Licensure and Certification Surveyor</p>