Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2135993	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Aurora Health Center Summit - Waukesha	**Street Address, City, State** W231 N1440 Corporate Ct, Waukesha, WI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a histology supervisor, the laboratory did not retain records of the lot number and expiration dates of stains and reagents used for hematoxylin and eosin (H&E) staining during 2021 or 2022. Findings include: 1. Review of laboratory records showed no evidence of records of the lot number or expiration dates of the stains and reagents used for H&E staining in 2021 or 2022. 2. Interview with a histology supervisor (staff A) on August 10, 2022 at 10:00 AM confirmed the laboratory did not retain records showing the lot number and expiration dates of the stains and reagents used for H&E staining.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures for tissue sample grossing and processing and interview with a histology supervisor, the laboratory director did not approve, sign and date the procedures used for patient testing. Findings include: 1. Review of laboratory procedures showed no evidence the laboratory director had approved the procedures. 2. Interview with a histology supervisor (staff A) on August

	10, 2022, at 9:55 AM confirmed the laboratory had no documentation to show the laboratory director approved, signed, and dated the procedures used for patient testing.