Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0431110	07/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Urologic Health Surgeons	2937 State Route 178, Utica, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisor and the Laboratory Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory process for assessing the competency of the Technical Supervisor and the Laboratory Supervisor. 2. During an interview on July 19, 2023 at 9:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology

	are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, statistical records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three non-gynecologic cytology statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual evaluation and comparison of three of three non-gynecologic cytology statistics documented by the laboratory. Statistics include: -Number of non-gynecologic cytology cases examined -Number of non-gynecologic specimens processed by specimen type -Number of non-gynecologic cases reported by diagnosis, including the number reported as unsatisfactory 2. During an interview on July 19, 2023 at 9:00 AM these findings were confirmed with the Laboratory Director /Technical Supervisor.
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