Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0357607	03/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bluffton Regional Medical Center	303 S Main St, Bluffton, IN	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for the laboratory's requirements for specimen handling and referral of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the following: a. Specimen labeling including patient name or unique patient identifier and when appropriate, specimen source; b. Specimen storage and preservation; c. Specimen processing; d. Specimen acceptability and rejection; e. Specimen referral. 2. During an interview on March 10, 2020 at 8:45 AM the Laboratory Manager confirmed there were no written procedures for specimen handling.
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 written policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for an annual evaluation of three required non-gynecologic annual statistics during the years 2018 and 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual evaluation of the following three required annual statistics: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. During an interview on March 10, 2020 at 8:45 AM the Laboratory Manager confirmed there were no written procedures for collection and review of annual statistics.
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