

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382519	(X3) Date Survey Completed 09/08/2023
Name of Provider or Supplier Mcfarland Clinic, Pc	Street Address, City, State 1215 Duff Avenue, Ames, IA	
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
D5629	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the annual cytology statistics and confirmed by identifier #1 (refer to the Laboratory Personnel Report) at 10:59 am on 9/8/2023, the laboratory failed to document the annual gynecologic and non-gynecologic statistics for 2022. The findings include: 1. For 2022, the laboratory documented a quarterly evaluation of: 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); d) the number of gynecologic case with diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; e) the number of gynecologic cases where cytology and histology are discrepant; and f) the number of 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. 2. At the time of the survey, the</p>

laboratory had not complied the above quarterly statistics into total annual statistics for 2022.