

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659542	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier D Randall Askins Md	Street Address, City, State 929 N Galloway Ste 202, Mesquite, TX	
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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 a review of the laboratory's policies, Center for Medicare & Medicaid Services (CMS) 116 form and staff interview, the laboratory failed to establish and follow written policies for non-gynecologic cytology cases to include an annual statistical evaluation of the number of cytology cases examined annually, number of specimens processed by specimen type and number of patient cases reported by diagnosis including the number reported as unsatisfactory for diagnostic interpretation. Findings included: 1. A review of the laboratory's policies revealed the laboratory failed to establish and follow written policies for an annual statistical laboratory evaluation of the number of cytology cases examined annually, number of specimens processed by specimen type and number of patient cases reported by</p>

diagnosis including the number reported as unsatisfactory for diagnostic interpretation. On 10/30/2021 at 10:35 a.m., the laboratory was asked to provide documentation of the laboratory's annual statistics for the number of cytology cases examined annually, the number of specimens processed by specimen type and the number of patient cases reported by diagnosis. No documentation was provided. 2. Review of the CMS 116 form, section VIII "Non-Waived Testing", had an estimated annual test volume of 400 tests for the sub-specialty of cytology (non-gynecologic). 3. During an interview on 10/30/24 at 11:40 a.m., the Laboratory Director confirmed the above findings.