

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2207494	(X3) Date Survey Completed 11/04/2024
Name of Provider or Supplier Diagnostic Pathology Services Llc	Street Address, City, State 16 Lilac Way, Skillman, NJ	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Laboratory Director (LD) the laboratory failed to establish corrective action procedures for BA for Histopathology and Cytology tests from 12/8/22 to 11/4/24. The finding includes: 1. The laboratory failed to have a procedure if a disagreement occurred with the BA results and the corrective action taken if it occurred. 2. The LD confirmed on 11/8/24 at 1:45 pm the laboratory did not establish corrective action procedures for the BA.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of the Users Manual (UM) for the Olympus BX41 microscope, the lack of temperature and humidity logs and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity where the Professional Component (PC) for Histopathology and Cytology tests were performed from 12/8/22 to 11/4/24. The findings include: 1. The UM for the Olympus BX41 microscopes defined the operating environment ambient temperature and humidity as 5 to 40C and a maximum humidity of 80% 2. There were no records of temperature or humidity in the room where the PC was being performed. 3. The LD confirmed on 11/4/24 at 1:35 pm the laboratory failed to monitor and document room temperature and humidity where the PC was being performed.

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 the lack of laboratory annual statistics records and interview with the Laboratory Director (LD), the laboratory failed to provide annual statistics records for six of the six required statistics for gynecologic and nongynecologic cytology test performed from 12/8/22 to 11/4/24 to the date of survey. Findings include: 1. The laboratory failed to provide an evaluation of six of the six required statistics. Statistics include: 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 to include unsatisfactory. d. Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison. e. Gynecologic cases where cytology and histology are discrepant. f. 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. The LD confirmed on 11/4/24 at 2: 00 pm the laboratory did not have the above annual statistical records.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual, the lack of records for slides examined each 24 hour period and interview with the Laboratory Director (LD), the laboratory failed to establish a procedure for work load limits within a 24 hour period from 12/8/22 to 11/4/24. The findings include: 1. There were no records or procedure available for review for the total number of slides examined by each individual each 24 hour period. 2. There were no records available for review for the number of hours each individual spent examining slides in the 24 hour period. 3. The LD confirmed on 11/4/24 at 2:05 pm that there was no procedure for workload limits established.