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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D2018531 | (X3) Date Survey Completed 01/19/2024 |
| Name of Provider or Supplier Pathology Laboratory, Inc, The | Street Address, City, State 2810 Ambassador Caffery Pkway, Lafayette, LA | |
| 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 | A Certification survey was performed on January 19, 2024 at The Pathology Laboratory, INC, CLIA ID # 19D2018531. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| D5637 | <p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) and workload reassessment records as well as interview with personnel, the laboratory failed to ensure that each individual's workload limit is reassessed every six (6) months and adjusted as necessary for six (6) of six (6) Technical Supervisors who performed the primary examination of cytology slides for one (1) of three (3) reassessments reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory listed the following personnel as Technical Supervisors: Personnel 1 Personnel 2 Personnel 3 Personnel 4 Personnel 5 Personnel 6 2. Review of the laboratory's 2022 and 2023 workload reassessment records revealed the laboratory performed workload reassessments in August 2022 and August 2023, but failed to perform a workload reassessment when due in February 2023. 3. In interview on January 19, 2024 at 12:33 p.m., the Compliance Officer confirmed the workload reassessment was not performed as identified above.</p> |
| D6079 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> |

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D5637.

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(c)(2)(3)

(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Supervisors failed to reassess the workload limits at least every six months for individuals that performed the primary examination of cytology slides. Refer to D5637.