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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0297371       | <b>(X3) Date Survey Completed</b><br><br>06/16/2025 |
| <b>Name of Provider or Supplier</b><br><br>Douglas K Pierce Md Pa  | <b>Street Address, City, State</b><br><br>8787 Bryan Dairy Rd Ste 360, Largo, FL |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | An announced CLIA recertification survey was conducted at Douglas K Pierce MD PA on 06/16/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:  |
| <b>D5415</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation and interview, inking supplies failed to be labeled to indicate the identity and expiration dates for five of five plastic storage containers. Findings include: 1. Five of five plastic storage containers in a rack at the grossing station on 6/16/25 at 9:51 a.m., were observed unlabeled to indicate the identity and expiration dates of what was stored in the five storage containers. 2. The Lab Manager on 6/16/25 at 9:51 a.m., stated the contents was the inking supplies used for the Histology testing performed by the laboratory. The Lab Manager confirmed the five containers were not labeled to indicate the identity and expiration dates of what was stored in the five storage containers.</p> |
| <b>D6120</b>              | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES<br/>CFR(s): 493.1451(b)(7)(8)</p> <p>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and</p>   |

complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Supervisor failed to evaluate the competency of two of three testing personnel and assuring that the staff maintained their competency following the laboratory's procedure. Findings include: 1. The CMS-209 Laboratory Personnel Report signed by the Lab Director 6/16/25 listed two laboratory staff listed as Testing Personnel (TP-B and TP-C) in addition to the Lab Director (TP-A). 2. The Technical Supervisor Job Description and Duties effective and approved by the Lab Director 3/1/25 stated Testing Personnel were to be evaluated at six months and 12 months during the first year of employment and yearly thereafter. 3. Personnel records for TP-B failed to include an annual evaluation of competency for 2024 and TP-C, who was employed as a Testing Personnel 3/2024, failed to include a six month evaluation of competency. 4. The Lab Manager confirmed on 6/16/25 at 10:00 a.m., personnel records for TP-B failed to include an annual evaluation of competency for 2024 and TP-C, who was employed as a Testing Personnel 3/2024, failed to include a six month evaluation of competency.