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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D0179913            | <b>(X3) Date Survey Completed</b><br>09/10/2025 |
| <b>Name of Provider or Supplier</b><br>Preferred Primary Care Physicians Inc   | <b>Street Address, City, State</b><br>2375 Greentree Road Suite 300, Carnegie, PA |   |
| 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>              | A recertification survey conducted by the Pennsylvania State Agency on 09/10/2025 found the Preferred Primary Care Phys Inc laboratory to be out of compliance with the following condition: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director  |
| <b>D3009</b>              | <p><b>FACILITIES</b><br/>CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on lack of documentation and interview with the Technical Supervisor (TS) #1, the Laboratory Director (LD) failed to be present for a reasonable period of each working day in each laboratory for which he is director for 23 of 23 months from 10 /18/2023 to the day of the survey as required by Pennsylvania (PA) state regulations. Findings Include: 1. Pennsylvania State Clinical Laboratory regulation 5.22(g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director". 2. On the day of the survey, 09/10/2025, the laboratory could not provide documentation of the director's onsite visits to the laboratory from 10/18/2023 to 09/10/2025. 3. Interview on 09/10/2025 at 9:13 am with TS #1 (PA State Laboratory Personnel #2) revealed the LD did not visit the laboratory for 23 of 23 months from 10/18/2023 to 09/10/2025 as required by PA regulations. 4. TS #1 confirmed the findings above on 09/10/2025 at 12:17 pm.</p> |
| <b>D6076</b>              | <p><b>LABORATORY DIRECTOR</b><br/>CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance</p>   |

with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute proficiency testing records, lack of documentation and interview with the technical supervisor, the laboratory director failed to provide overall management and direction in accordance with 493.1445. The laboratory director failed to ensure proficiency testing samples were tested as required under subpart H in 2024. Refer to D6089

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with the Technical Supervisor (TS), the laboratory director (LD) failed to ensure PT samples were tested as required under subpart H in 2024 for 5 of 5 PT events performed for Chemistry, 3 of 3 PT events performed for Microbiology and 1 of 3 PT events performed for Hematology. Findings include: 1. On the day of the survey 09/10/2025, review of the laboratory's API PT records revealed, the laboratory director (LD)/designee failed to document the attestation of the routine integration of samples into the patient workload for the following API PT events in 2024: - Chemistry Core: 1st, 2nd and 3rd Events of 2024 API. - Chemistry Miscellaneous: 1st and 2nd Events of 2024 API. - Microbiology 1st, 2nd and 3rd Events of 2024 API. - Hematology/Coagulation: 3rd Event of 2024 API. 2. The TS confirmed the findings above on 09/10/2025 at 12:31 pm. \*\*Repeat Deficiency\*\*