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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>06D2267171           | <b>(X3) Date Survey Completed</b><br><br>12/24/2025 |
| <b>Name of Provider or Supplier</b><br><br>Peak Clinical Diagnostics Llc   | <b>Street Address, City, State</b><br><br>2600 S Parker Road Suite 2-125, Denver, CO |   |
| 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>              | The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing provider. The facility was found to be out of compliance with the conditions of the CLIA program. The following condition level deficiencies were found to be out of compliance: 42 C.F.R. 493.803 Condition: Successful Participation [proficiency testing];   |
| <b>D2016</b>              | <p><b>SUCCESSFUL PARTICIPATION</b><br/>CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on a routine desk review of the CMS-155 report for proficiency testing performance and review of proficiency testing evaluation reports from the proficiency</p> |

testing provider, American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance scores for two consecutive events for RBC, HCT (non-waived), and HGB (non-waived) proficiency testing for event 1 in 2025 and event 2 in 2025, see D2130. Additionally, the laboratory failed to achieve an overall satisfactory performance score for Hematology for two consecutive events (event 1 in 2025 and event 2 in 2025), see D2131.

**D2130**

**HEMATOLOGY**  
CFR(s): 493.851(f)

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on a review of the CMS-155 Individual Laboratory Profile report for proficiency testing (PT) performance and a review of the proficiency testing evaluation report provided by the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance scores for RBC, HCT (non-waived), and HGB (non-waived) proficiency testing for event 1 in 2025 and Event 2 in 2025. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on 12/24/2025 at 11:30 AM, revealed the RBC score for event 1 in 2025 was 60%, and the score for event 2 in 2025 was 60%; the HCT (non-waived) score for event 1 in 2025 was 60%, and the score for event 2 in 2025 was 60%, the HGB (non-waived) score for event 1 in 2025 was 60%, and the score for event 2 in 2025 was 60%. 2. A review of the PT evaluation report from the provider, API, on 12/24/2025 at 12:00 PM revealed the RBC score for event 1 in 2025 was 60%, and the score for event 2 in 2025 was 60%; the HCT (non-waived) score for event 1 in 2025 was 60%, and the score for event 2 in 2025 was 60%, the HGB (non-waived) score for event 1 in 2025 was 60%, and the score for event 2 in 2025 was 60%.

**D2131**

**HEMATOLOGY**  
CFR(s): 493.851(g)

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on a review of the CMS-155 Individual Laboratory Profile report for proficiency testing (PT) performance and a review of the proficiency testing evaluation report provided by the American Proficiency Institute (API), the laboratory failed to achieve overall satisfactory performance scores for Hematology for event 1 in 2025 and Event 2 in 2025. Findings include: 1. A review of the CMS-155 Individual Laboratory Profile on 12/24/2025 at 11:30 AM, revealed the overall Hematology proficiency testing score for event 1 in 2025 was 79%, and the score for event 2 in 2025 was 62%. 2. A review of the PT evaluation report from the provider, API, on 12/24/2025 at 12:00 PM revealed the overall Hematology proficiency testing score for event 1 in 2025 was 79%, and the score for event 2 in 2025 was 62%.