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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D0543719    | <b>(X3) Date Survey Completed</b><br><br>02/12/2020 |
| <b>Name of Provider or Supplier</b><br><br>Privilege Dx Medical Laboratories, Inc  | <b>Street Address, City, State</b><br><br>10133 Riverside Dr, Toluca Lake, CA |   |
| 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>D2121</b>              | <p>HEMATOLOGY<br/>CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on Surveyor review of proficiency testing (PT) records from American Association of Bioanalysts (AAB) and interview with the laboratory Technical Supervisor, the laboratory failed to attain at least 80% score for Lymphocyte and Neutrophil in the 3rd event of 2019, and is determined unsatisfactory analyte performance. The findings include: a. The PT records of the 3rd event of 2019 shows that the laboratory obtained "40%" score for the analyte Neutrophil and "60%" score for the analyte Lymphocyte. b. PT sample results review and an interview with the laboratory Technical Supervisor on 02/12/2020 at 2:50 pm, confirmed that the laboratory received the following scores: Sample ID Reported Result Expected Result (Neutrophil %) 2 52.3 56.0 - 61.0 3 52.8 37.8 - 51.4 5 52.8 55.9 - 61.1 Sample ID Reported Result Expected Result (Lymphocyte %) 2 33.0 11.1 - 20.9 5 33.1 11.0 - 20.7 c. The laboratory's testing declaration form signed by the laboratory director on 2/10/2020 shows that the laboratory runs 11,374 WBC differentials tests, annually.</p> |
| <b>D6095</b>              | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on Surveyor review of proficiency testing records, and interview with the</p>  |

laboratory Technical Supervisor and testing personnel, it was determined that the laboratory Director failed to ensure the maintenance of acceptable levels of analytical performance for each test system. See D2121.