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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D0940311                   | <b>(X3) Date Survey Completed</b><br><br>10/05/2021 |
| <b>Name of Provider or Supplier</b><br><br>Pardee Cancer Center  | <b>Street Address, City, State</b><br><br>805 6th Avenue West, Suite 100, Hendersonville, NC |   |
| 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>D5785</b>              | <p><b>CORRECTIVE ACTIONS</b><br/>CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the Hematology analyzers' manufacturer's instructions and review of the 2019, 2020, and 2021 temperature and humidity logs 10/5/21, the laboratory failed to ensure corrective action was taken and documented for humidity readings outside the acceptable limits. Findings: Review of the manufacturer's instructions for the operating environment of the AcT Diff(previous hematology analyzer) and the Sysmex XN-530(current hematology analyzer) revealed room humidity limits of 20-85%(percent). Review of 2019, 2020, and 2021 temperature and humidity logs revealed the room humidity was outside the acceptable limits of 20-85% on the following days with no corrective action documented: a. 4 of 22 days in January 2020 - 1/21, 1/22, 1/23, 1/24; b. 1 of 20 days in January 2021 - 1/29; c. 2 of 20 days in February 2021 - 2/3, 2/4; d. 4 of 23 days in March 2021 - 3/5, 3/8, 3/9, 3/10; e. 2 of 22 days in April 2021 - 4/2, 4/5.</p> |