

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  30D2149259	<b>(X3) Date Survey Completed</b>  10/26/2018
<b>Name of Provider or Supplier</b>  Elliot Urgent Care Lab At Bedford	<b>Street Address, City, State</b>  25 Leavy Dr, Bedford, NH	
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>
<b>D5425</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to determine hematology test system's control procedures based upon the performance specifications established by the laboratory in 2018. Findings include: 1) Review on 10/26/2018 the laboratory's control procedure for prothrombin/international normalized ratio (PT/INR) revealed instruction to test two levels of PT/INR controls for each new lot or shipment of reagent test cartridges and every 30 days. 2) Review on 10/26/2018 of the i-STAT manufacturer's instructions revealed instruction to perform control testing on each new lot and shipment of PT/INR test cartridges. 3) Review on 10/26/2018 of the laboratory individualized quality control procedure for PT/INR revealed the data used to determine the quality control procedure (QCP) was obtained in 2015 and 2016 by other laboratories. This laboratory did not establish its own performance specifications using its own i-STAT analyzers to determine the QCP for PT/INR. 4) Interview on 10/26/2018 at 11:30 a.m. with the technical consultants confirmed the above findings. 5) The laboratory has performed two PT/INR tests since opening in July 2018.</p>