

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2040017	<b>(X3) Date Survey Completed</b> 07/21/2023
<b>Name of Provider or Supplier</b> University Health System	<b>Street Address, City, State</b> 1130 Middle Creek Rd, Suite 160, Sevierville, TN	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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: Hematology: The laboratory failed to maintain satisfactory participation in two consecutive events for the Cell I.D. or WBC Diff analyte resulting in the initial unsuccessful proficiency testing (PT) occurrence for Cell I.D. of WBC Diff (Refer to D2130)</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a Proficiency Testing (PT) desk review of the CMS CASPER Report 0155D and the laboratory's 2023 Proficiency Testing (PT) performance summary records from the College of American Pathologists (CAP) Proficiency Testing program, the laboratory failed to maintain satisfactory performance for the Cell I.D. or WBC Diff analyte in the 1st event 2023 and 2nd event 2023, resulting in the initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 0155D report revealed unsatisfactory Cell I.D. or WBC Diff analyte scores of 0% for the 1st and 2nd events of 2023. 2. A review of the laboratory's CAP Proficiency Testing records revealed unsatisfactory Cell I.D. or WBC Diff analyte scores of 0% for the 1st and 2nd events of 2023, resulting in the initial unsuccessful PT occurrence.