

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0040942	<b>(X3) Date Survey Completed</b>  04/06/2021
<b>Name of Provider or Supplier</b>  Umd Health Services Laboratory	<b>Street Address, City, State</b>  615 Niagara Ct, Duluth, MN	
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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate unacceptable Hematology proficiency testing (PT) results for 1 analyte in 2019. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Consultant 1 (TC1) during the entrance interview at 10:05 a.m., on 04/06/21. 2. The laboratory performed PT using the College of American Pathologists (CAP) program. 3. The laboratory received unacceptable Red Blood Cell Count (RBC) PT results in 1 of the 13 scheduled PT events completed in 2019. See below. CAP 2019 Hematology Auto Differential (FH1-A) event Sample Test FH1-02 RBC FH1-04 RBC 4. Investigation of the unacceptable PT results was required as established in the Quality Assurance Policy located in the Procedure Manual - UMD Health Services Laboratory. 5. Investigation of the unacceptable PT results were not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12:45 a.m., on 04/06/21, TC1 confirmed the above findings. .</p>