

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0893316	(X3) Date Survey Completed 03/04/2019
Name of Provider or Supplier Student Health Services University Of Memphis	Street Address, City, State 3770 Desoto Ave, Memphis, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records and interview with the laboratory liaison, the laboratory director failed to sign the attestation statements for two of three events in 2017 (events two and three). The findings include: 1) Review of the laboratory proficiency testing records revealed the attestation statements for Hematology/Coagulation 2017 event two and three were not signed by the laboratory director. 2) Interview with the laboratory liaison on March 4, 2019 at 10:30 am confirmed the laboratory director failed to sign attestation statements for Hematology /Coagulation 2017 events two and three.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation of the laboratory, review of the verification of performance specification (VoPS) studies performed for the complete blood count (CBC) instrument and interview with the laboratory liaison, the laboratory failed to verify the manufacturer reference intervals (normal patient range) for the Sysmex XN-430 CBC instrument in 2017. The findings include: 1) Observation of the laboratory on March 4, 2019 at 9:00 am revealed the Sysmex XN-430 CBC instrument in use for patient testing. 2) Review of the VoPS studies approved on 12.20.2017 for the Sysmex XN-430 CBC instrument revealed the manufacturer patient normal ranges were not verified. 3) Interview with the laboratory liaison on March 4, 2019 at 11:30 am confirmed the laboratory failed to verify the Sysmex XN-430 manufacturer normal patient range in 2017. The laboratory uses the manufacturer normal patient ranges.