

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1073878	(X3) Date Survey Completed 07/19/2019
Name of Provider or Supplier Overlook Medical Ctr Satellite Emergency Dept Lab	Street Address, City, State 1000 Galloping Hill Road, Union, NJ	
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: from September 2016 Based on surveyor review of the Individualized Quality Control Plan (IQCP) for the Abbott iStat and interview with the General Supervisor (GS), the laboratory failed to establish and document the number, type and frequency of testing control material before implementing the IQCP from September 2016 to the date of the survey. The GS confirmed on 7/19/19 at 2:00 pm that the laboratory did not have a Quality Control procedure in the IQCP.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to identify problems on the FR for Hematology and Chemistry results on the date of the survey. The findings include: 1. The FR had an Asterisk (*) next to all results with a comment " - new results". 2. The IT department stated via telephone the * was for the first time results were printed but a review of three patient charts revealed the * remained on the report after results had been printed. 3. The interpretation of the * did not indicate it referred to printing or a repeated results. 4. The GS confirmed on 7/19/19 at 1:15 pm that the laboratory did not identify problems on the final report.