

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0274682	(X3) Date Survey Completed 10/11/2018
Name of Provider or Supplier Adventhealth Medical Group Cardiology At Orlando	Street Address, City, State 1613 N Mills Ave, Orlando, FL	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to meet the manufacturer's criteria for acceptability for the external liquid quality control (QC) low level before reporting patient test results. Findings: Review of the "Oxicom External Liquid QC Worksheet," showed that on 6/12/18 the low control for serial number 4940.463 was reported as 50.3. The low level of external liquid controls according to the "Waters Medical Systems Manufacturing Certification" for serial number 4940.463 showed the range for the low level external liquid control was 51.0 to 65.0. Documentation of the corrective action on the "Oxicom External Liquid QC Worksheet" indicated that no corrective action was documented. During an interview on 10/11/18 at approximately 11:40 AM, the lab manager acknowledged that the low level of external liquid controls was out of range and no corrective action was documented.</p>