

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0968266	(X3) Date Survey Completed 05/17/2019
Name of Provider or Supplier Cardiology Associates Of North Ms	Street Address, City, State 2459 5th St N, Columbus, MS	
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 review of quality control (QC) records for the Accumetrics Verify NOW system from 1/2/18 through 4/24/19 and patient's electronic medical record, the laboratory failed to ensure at least two levels of control material met the manufacturer's criteria for acceptability on 4/24/19, when one patient platelet aggregation test was performed and results reported. Findings include: Review of QC records for the Accumetrics Verify NOW system from 1/2/18 through 4/24/19 and patient's electronic medical record revealed on 4/24/19, the Level 2 control, of two levels, was outside the manufacturer's acceptable range when platelet aggregation testing was performed and results reported for Patient #002430320.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
Based on review of Creatine Kinase-MB (CK-MB), Troponin I, and Platelet Aggregation test reports in patients' electronic medical records and interview with Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 Personnel Form, on 5/17/19 at 9:40 a.m., laboratory reports reviewed in the current electronic medical record system did not include the name and address of the laboratory location where the tests were performed. Findings include: Review of test reports in the following patients' electronic medical records revealed the patient test reports did not include the name and address of the laboratory location where the tests were performed: Patient #002613883 - platelet aggregation test performed 4/18 /19. Patient #004733804 - CK-MB and Troponin I tests performed 5/6/19. Interview with Testing Personnel #2 on 5/17/19 at 9:40 a.m. revealed the current electronic medical record system was put in use on 4/17/19.