

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0882434	(X3) Date Survey Completed 10/01/2018
Name of Provider or Supplier Medical Group Lancaster	Street Address, City, State 44469 10th St W, Lancaster, CA	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review and the lack of documentation for quality control (QC) performance, random patient sampling test results reviewed, and interview with the technical consultant, it was determined that the laboratory failed to at least once a day patient specimens are assayed or examined perform the each quantitative procedure, include two control materials of different concentrations for Troponin analyte. The findings included a. Based on the laboratory's annual testing volume submitted for 2017-2018 for Troponin analyte, the laboratory analyzed and reported 13 tests. b. The technical consultant affirmed (10/1/2018, 1330) that the laboratory has no documentation to show of QC performance for Troponin analytes.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review and the lack of documentation for quality control (QC) performance, random patient sampling test results reviewed, and interview with the technical consultant, it was determined that the laboratory failed to at least once a day patient specimens are assayed or examined perform the each quantitative procedure, include two control materials of different concentrations. The findings included a. Based on the laboratory's annual testing volume submitted for 2017-2018 for Troponin analyte, the laboratory analyzed and reported 13 tests. b. The technical consultant affirmed (10/1/2018, 1330) that the laboratory has no documentation to show of QC performance for Routine Chemistry testing.