

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0553670	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Cor Healthcare Medical Associates	Street Address, City, State 1360 W 6th Ste 315, San Pedro, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of 2016 proficiency testing reports from CMS (report 155D, Individual Profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing documents for the Alfa Wasserman ACE Axcel chemistry testing system, and patients' test records; and interview with the Testing Person, the laboratory failed to attain a score of at least 80% for AST (Aspartate aminotransferase /SGOT) in the 3rd event, constituting unsatisfactory analyte performance. Findings include: a. CMS and AAB reported the unsatisfactory score of 60% for AST for the final event of 2016. b. The Technical Consultant and Testing Person-1 affirmed (11/16 /17) the aforementioned unsatisfactory score; constituting unsatisfactory test performance for AST during the timeframe September - December 2016. c. The reliability and quality of AST results reported during September to December 2016 could not be assured. Based on the estimated annual test volume of 1,160, the laboratory reported approximately 96 AST results each month. A few examples are as follows: Date Number of one Accession # results reported ----- ----- 10/21/16 16 611393849 11/08/16 72 611394162 12/14/16 65 611394366</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
 Based on review of 2016 -2017 proficiency testing reports from AAB (American Association of Bioanalysts) and interview with the Technical Consultant, the laboratory failed to verify the accuracy of their CO2 testing in 2016 - 2017. Findings include: a. The laboratory chose to participate in AAB's proficiency testing program as the means to satisfy the requirement to verify the accuracy of testing for CO2. b. AAB reported unsatisfactory scores for 4 out 4 consecutive events as follows: Year Event Score ----- 2016 3 20% 2017 1 40% 2017 2 20% 2017 3 60% c. The Technical Consultant affirmed (11/16/17) the aforementioned unsatisfactory scores, and thus, the laboratory failed to demonstrate and verify accurate testing for CO2 for numerous consecutive months. d. The reliability and quality of CO2 results reported in 2016 through 2017 could not be assured with failures in accuracy of testing. Based on the stated estimated annual test volume of 1,218; the laboratory reported approximately 152 results for CO2 tests each month, excluding March to June 2017. A few examples are as follows: Date Number of one Accession # results reported ----- 10/21/16 16 611393860 11/08/16 72 611394162 12/14/16 65 611394366 1/20/17 77 611394886 2/08/17 65 611395157 7/11/17 12 611395795 8/31/17 18 611396627 9/14/17 80 611396806 10/18/17 117 611397356

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:
 Based on review of laboratory proficiency testing documents and patients test reports, the lack of laboratory documents, and interview with the Technical Consultant, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings include: a. The laboratory failed to have a written policy or procedure for an ongoing practice to monitor, assess, and correct problems identified in the analytic systems; and to not report results until the problem(s) is corrected. b. See D5217