

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1064850	(X3) Date Survey Completed 06/14/2019
Name of Provider or Supplier Altasciences Los Angeles	Street Address, City, State 5630 Cerritos Ave, Cypress, 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
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(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 first quarter (Q1-2018) of the College of American Pathologists (CAP) proficiency testing records, random patient sampling test results, interview with the technical consultant and laboratory personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Human Chorionic Gonadotropin Hormone (HCG) analyte. The findings included: a. Q1-2018, CAP reported an unacceptable for samples K-02 and K-04, resulted with a score of 60%. b. For six (6) out of six (6) random patient sampling test results reviewed covering period from 2/28/2018 to 1/3 2019, the laboratory analyzed and reported approximately 1,000 HCG quantitative tests during the period the laboratory received the unsatisfactory proficiency testing score. c. The technical consultant and the laboratory personnel confirmed (6/14/2019, 12:45) that the laboratory received the above unsatisfactory proficiency testing score for HCG.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on reviews of the College of American Pathologists (CAP) proficiency testing records, random patient sampling test results and interview with the technical consultant and laboratory personnel, it was determined that the laboratory failed to follow manufacturer's test system instructions in reporting International Sensitivity Index (ISI) value. The findings included: a. Per manufacturer's insert for Sysmex CS 2500, ISI value is 1.07, but the laboratory reported ISI 0.97 value, resulting in an unacceptable INR results for Q1-2018. CAP reported unacceptable results (60%) for samples CGL-02 and CGL-05 International Normalized Ratio (INR). b. For eight (8) out of eight (8) random patient sampling test results reviewed covering period from 2/22/2017 to 1/3 2019, the laboratory analyzed and reported approximately 6,000 Prothrombin Time/International Normalized Ratio (PT/INR) tests during the period the laboratory received the unsatisfactory proficiency testing score. c. The technical consultant and the laboratory personnel confirmed (6/14/2019, 12:45) that the laboratory reported an incorrect ISI Value which resulted in an erroneous INR calculations