

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0559170	<b>(X3) Date Survey Completed</b>  11/20/2018
<b>Name of Provider or Supplier</b>  Los Angeles Heart Specialists	<b>Street Address, City, State</b>  18370 Burbank Blvd, Ste 401, Tarzana, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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> <p>This STANDARD is not met as evidenced by: Based on review of the first quarter (Q1-2018), second quarter (Q2-2018) of the Medical Laboratory Evaluation (MLE) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to 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. The findings included: a. Hematology: Q1-2018, MLE reported unsatisfactory score of 0% for Sedimentation Rate (Westergren) analyte. b. Endocrinology: Q1-2018, MLE reported unsatisfactory scores for the following analytes; 50% for Follicle Stimulating Hormone (FSH) 0% for Luteinizing Hormone (LH) Q2-2018, MLE reported unsatisfactory score of 0% for Parathyroid Hormone, Intact (PTH) analyte. c. Chemistry: Q1-2018, MLE reported unsatisfactory score of 0% for Vitamin B12 analyte. d. For thirteen (13) out of thirteen (13) random patient test results reviewed covering period from 9/1/2016 to 10/29/2018, the laboratory analyzed and reported during the period when the proficiency testing scores were unsatisfactory for the above analytes. e. The technical consultant confirmed (11/20/2018, 14:20) that the laboratory received the above unsatisfactory proficiency testing scores.</p>
<b>D5803</b>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p>

This STANDARD is not met as evidenced by:  
Based on review of random patient sampling test results and the lack of antimicrobial sensitivity results on the patient's chart, and interview with the technical supervisor, 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 postanalytic systems. The findings included: a. Based on review of random patient sampling test results, the laboratory has no documentation of antimicrobial sensitivity results on the patient's chart. b For one (1) out of four (4) random patient sampling test results reviewed covering period from 11/2/2016 to 2/12/2018, one (1) patient with an order of urine culture and sensitivity did not have the sensitivity results on the patient's chart. c. The technical supervisor confirmed (11/20/2018, 14:20) that the laboratory failed to ensure that test results are maintain on the patient's chart.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
Based on review of random patient sampling test results and the lack of antimicrobial sensitivity results on the patient's chart, and interview with the technical supervisor, 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 postanalytic systems. See D 5803.