

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0592241	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Eurofins Ascend Clinical, Llc	Street Address, City, State 435 Oakmead Parkway, Sunnyvale, 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 review of second quarter (Q2-2016) of the College of the American Pathologists (CAP) proficiency testing records, CMS 96D Casper report, random patient sampling test results and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each Thyroid Stimulating Hormones (TSH) analyte. The findings included: a. Q2-2016, CAP reported a score of 0% for TSH proficiency testing challenges. b. For three (3) out of three (3) random patient sampling test results reviewed covering period from 2/1/2017 to 10/6/2017, three (3) could have been affected by the TSH proficiency failure. c. The technical consultant confirmed (11/6 /2018, 16:45) that the laboratory received the above unsatisfactory proficiency testing score for TSH analyte.</p>
D2109	<p>TOXICOLOGY CFR(s): 493.845(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 review of second quarter (Q2-2016) of the College of the American Pathologists (CAP) proficiency testing records, CMS 96D Casper report and interview with the technical consultant, it was determined that the laboratory failed to attain a</p>

score of at least 80 percent of acceptable responses for each Phenytoin analyte. The findings included: a. Q2-2016, CAP reported a score of 60% for Phenytoin proficiency testing challenges. b. Based on the laboratory's annual testing declaration submitted for 2016-2018, the laboratory analyzed and reported 34,937 Toxicology tests which included Phenytoin analyte. c. The technical consultant confirmed (11/6/2018, 16:45) that the laboratory received the above unsatisfactory proficiency testing score for Phenytoin analyte.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on review of first quarter (Q1-2017) of the College of the American Pathologists (CAP) 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. Q1-2017 CAP reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Urine BUN 33% Q1/2017 Vit D 66.7% Q1-2017 b. Based on the laboratory's annual testing volume submitted for 2016-2018, the laboratory analyzed and reported 7,338,076 Routine Chemistry which included Urine BUN analytes. c. For three (3) out of three (3) random patient sampling test results reviewed for Vitamin D analytic, covering period from 12/30/2016 to 10/3/2017, three (3) Vitamin D test were analyzed and reported during the period the laboratory received an unsatisfactory Vitamin D proficiency testing score. d. The technical consultant confirmed (11/6/2018, 16:45) that the laboratory received the above unsatisfactory proficiency testing scores for Urine BUN and Vitamin D analytes.