

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0553994	<b>(X3) Date Survey Completed</b> 12/06/2021
<b>Name of Provider or Supplier</b> Centers For Family Medicine Db a Optum	<b>Street Address, City, State</b> 5500 E Atherton St Ste 416, Long Beach, 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>D2099</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) proficiency testing reports, review of five (5) randomly selected patient result records from 06/16/2021 to 10/21/2021, and interview with the laboratory testing person (TP), the laboratory failed to attain a score of at least 80 percent for Endocrinology C-peptide analyte. The findings included: 1. The API third event for 2021 (Q3-2021) reported a proficiency testing score of 50% for the C-peptide analyte giving the subspecialty of Endocrinology a 50% overall score. 2. The TP confirmed on 12/6/2021 at approximately 11:00 a.m. that the laboratory had failed to attain a proficiency score of at least 80 percent for the C-peptide analyte. 3. Based on the laboratory's annual test volume declaration signed by the laboratory director on 12/6/2021 the laboratory analyzed and reported approximately 2,202 Endocrinology tests which include C-peptide.</p>
<b>D2105</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:  
Based on review on the proficiency testing (PT) performance records, corrective actions record for the years of 2021, and interview with the laboratory testing person (TP) on December 6, 2021; the laboratory failed to document any remedial actions or training for unsatisfactory C-peptide PT performance. The findings include: 1. The laboratory participated in the American Proficiency Institute PT program for the year 2021, obtaining an unsatisfactory analyte performance for C-peptide; however, the laboratory failed to document any corrective actions or training for unsatisfactory analyte performance. 2. The TP affirmed on December 6, 2021 at approximately 11:30 a.m. that the laboratory received an unsatisfactory score for C-peptide analyte for the Q3-2021 event and did not document any remedial actions or training for the unsatisfactory performance. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/6/2021, stated that the laboratory performs approximately 2,202 Endocrinology tests annually

**D6073**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(4)

Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.

This STANDARD is not met as evidenced by:  
Based on review of proficiency testing records, corrective action reports, and interview with the testing person; the testing person failed to follow established corrective action policies and procedures on documentation of remedial actions and training when proficiency results are unsuccessful. see D2099 and D 2105.