

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0894925	<b>(X3) Date Survey Completed</b>  10/09/2019
<b>Name of Provider or Supplier</b>  Cdt Toa Alta	<b>Street Address, City, State</b>  Calle Barcelo Numero 16, Toa Alta, PR	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on Proficiency Testing record (year 2019), Creatine Kinase Isoenzyme (CK-MB) testing record review and general supervisor interview on October 9, 2019 at 12:30 PM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for CK-MB test from April 1, 2019 to October 9, 2019 when 96 out of 96 CK-MB patients specimens were processed and reported by the Vitros 350 system. The findings include: 1. On October 9, 2019 at 12:30 PM, the Proficiency Testing record showed that the laboratory did not enroll in an HHS approved Proficiency Testing Program for CK-MB test during the year 2019. 2. The CK-MB testing record showed that the laboratory processed and reported 96 out of 96 patients specimens by the Vitros 350 system from April 1, 2019 to October 9, 2019. 3. The general supervisor confirmed on October 9, 2019 at 12:30 PM that the laboratory did not participate in an HHS approved Proficiency Testing Program for CK-MB from April 1, 2019 to October 9, 2019.</p>
<b>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p>

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on Proficiency Testing record (year 2019), Creatine Kinase Isoenzyme (CK-MB) testing record review and general supervisor interview on October 9, 2019 at 12:30 PM, it was determined that the laboratory director failed to fulfill her responsibilities to comply with the laboratory Proficiency Testing requirements. Refer to D 6088 (The laboratory director did not enroll the laboratory in an HHS approved Proficiency Testing Program for CK-MB test from April 1, 2019 to October 9, 2019 when 96 out of 96 CK-MB patients specimens were processed and reported by the Vitros 350 system).

**D6088**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Based on Proficiency Testing record (year 2019), Creatine Kinase Isoenzyme (CK-MB) testing record review and general supervisor interview on October 9, 2019 at 12:30 PM, it was determined that the laboratory director did not enroll the laboratory in an HHS approved Proficiency Testing Program for CK-MB test from April 1, 2019 to October 9, 2019. Refer to D 2000.