

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2113345	<b>(X3) Date Survey Completed</b>  11/09/2021
<b>Name of Provider or Supplier</b>  Heart Health Center Llc	<b>Street Address, City, State</b>  1848 E Thomas Rd, Ste 200, Phoenix, AZ	
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><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 lack of Proficiency Testing (PT) records for 2019, 2020 and 2021, through the date of the survey, and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for regulated testing performed in the specialty of Chemistry, which are included in subpart I . Findings include: 1. The laboratory began blood gas testing on the i-Stat analyzer on August 8, 2019. The laboratory utilizes the CG8+ test cartridge which includes the following analytes: pH, pCO2, pO2, HCO3, TCO2, SO2, Sodium, Potassium, ionized Calcium, Glucose, Hematocrit and Hemoglobin. 2. No documentation was presented for review during the survey conducted on November 9, 2021 to indicate the laboratory was enrolled during 2019, 2020 and the first event of 2021 in a CMS-approved PT program for regulated testing listed in subpart I, Blood gas (pH, pO2, pCO2), for which the laboratory performed patient testing. 3. The technical consultant confirmed that the laboratory failed to enroll and participate in PT for blood gas testing until the 3rd testing event of 2021. 4. The laboratory's approximate annual test volume for blood gas testing is 100.</p>
<b>D6033</b>	<b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b>

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6041 - failure to ensure that the laboratory was enrolled and participated in an HHS approved Proficiency Testing program for testing performed by the laboratory.

**D6041**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on lack of Proficiency Testing (PT) records from 2019, 2020 and 2021 (through the 3rd testing event), for the regulated Blood gas (pH, pO<sub>2</sub>, pCO<sub>2</sub>) analytes and interview with the Technical Consultant, it was determined that the technical consultant failed to ensure that the laboratory was enrolled and participated in an HHS approved PT program for testing performed by the laboratory. See D2000 for findings.