

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D1106278	<b>(X3) Date Survey Completed</b> 04/02/2021
<b>Name of Provider or Supplier</b> Heart Care Consultants Llc	<b>Street Address, City, State</b> 5600 Chestnut Street, Philadelphia, PA	
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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the technical consultant (TC), the laboratory failed to establish a maintenance and function check protocol for 2 of 2 unlabelled thermometers used to monitor Abbott istat cartridges and reagents stored in the refrigerator and room temperature the from 04/11/2019 to 04/02/2021. Findings include: 1. On the day of survey, 04/02/2021, the surveyor observed 1 of 1 unlabeled refrigerator thermometer and 1 of 1 La Crosse Technology room temperature thermometer in use to monitor the temperatures of Abbott istat cartridges and reagents used on the Abbott istat. 2. The laboratory could not provide a maintenance and function check protocols or documentation of maintenance and function performed on of 1 unlabeled refrigerator thermometer and 1 of 1 La Crosse Technology room temperature thermometer from 04/11/2019 to 04/02/2021. 3. The TC confirmed the findings above on 04/02/2021 around 11:50 am.</p>
<b>D6004</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manuals and interview with the technical consultant (TC), the laboratory director (LD) failed to follow laboratory procedures and perform yearly technical consultant (TC) competency assessment in 2019, 2020 and 2021. Findings include: 1. The Laboratory Competency Assessment Policy states, "Competency assessment of the technical consultant will be done by the laboratory director". 2. On the day of survey, 04/02/2021, the TC could not provide their competency assessment documentation from 2019, 2020 and 2021. 3. The TC confirmed on 4/02/2021 around 10:15 am, they were not assessed for competency by the LD.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency test (PT) records and interview with the technical consultant (TC), the Laboratory Director (LD) failed to ensure that all proficiency testing reports received were reviewed by appropriate staff from 2019 to 2021. Findings include: 1. On the day of survey, 04/02/2021, review of API PT records revealed: - API 2019 3rd Event, Chemistry - 0% corrective actions were not documented and the attestation sheet was not signed by LD. - API 2020 1st Event, Chemistry Attestation was not signed by LD and/or testing personnel and Potassium 80% corrective actions were not documented. - API 2020 3rd Event, Chemistry- Calcium 80% and Glucose 80%, corrective actions were not documented. 2. The TC confirmed the findings above on 04/02/2021 around 10:15 am.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of quality control records and interview with technical consultant (TC), the laboratory failed to perform external liquid quality controls (QC) of different concentration, each day of patient testing for the Activated Clotting Time (ACT), Protrombin Time (PT)/ international normalized ratio (INR) and Chemistry (Chem) 8 cartridges analyzed on the Abbott istat in 2019, 2020 and 2021. Findings include: 1. On the days of survey, 04/02/2021, review of laboratory quality control records revealed, the laboratory did not perform external quality control for of different concentrations on the ACT, PT/ INR and Chem 8 cartridges analyzed on the Abbott istat in 2019, 2020 and 2021. 2. The TC confirmed the findings above on 04/02/2021 around 11:00 am.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records, proficiency testing (PT) records and interview with the technical consultant (TC), the TC failed to assess the competency for 4 of 5 testing personnel (TP) through internal blind testing samples or external PT samples for hematology testing performed in 2020. Findings Include: 1. On the day of survey, 04/02/2021, review of PT records and TP competency assessment records revealed the laboratory did not assess the test performance of TP through internal blind testing samples or external PT samples for 4 of 5 TP who performed Activated Clotting time and Prothromin Time on the Abbott istat in 2020. 2. The TC confirmed the findings above on 04/02/2021 around 10:00 am.