

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2135236	(X3) Date Survey Completed 10/06/2022
Name of Provider or Supplier Heart And Health, Pllc	Street Address, City, State 6175 Sunrise Highway, Massapequa, NY	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's records API Proficiency Testing (PT) the laboratory failed to include CEA as part of PT module for year 2020 through survey date. It was confirmed on an interview with the laboratory technical consultant on 10/6 /2022 about 2pm.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the technical consultant, the laboratory failed to establish written policies and procedures for specimen storage. FINDINGS: 1. The laboratory failed to provide written policies and procedures for specimen storage. 2. The laboratory failed to provide temperature log of patient specimen storage refrigerator. 3. The technical</p>

consultant confirmed on 10/6/2022 at approximately 2pm, the laboratory failed to establish written policies and procedure of blood specimens storage.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on the review of New Control Lot Validation Method procedure and lack of new control lot validation records for Beckman AU680, Beckman DXH800, Tosoh G8 and Beckman DXI600, the laboratory failed to follow the procedure to validate by running new lot control 20 times over 5 days. The technical consultant confirmed in an interview on 10/6/2022 about 12:00pm, the laboratory failed to follow the written procedure.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on the lack of a standard laboratory manual for Beckman DXH 800 and Tosoh G8, the laboratory failed to establish a written Standard Operations Procedure (SOP) manual laboratory. Findings: 1. Accordance with D5403(b)(3), the laboratory failed to Step-by-step performance of the procedure, including test calculations and interpretation of results. 2. The laboratory failed to establish policy and procedure monitoring and reviewing of the laboratory's test reports (i.e., patient information, test results, normal ranges, and the disposition of unacceptable specimens), and the laboratory's turn-around times of laboratory report review. 3. The technical consultant confirmed in an interview on 10/6/2022 about 12:30pm, the laboratory failed to have a written SOP for the lab.

<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on the review of calibration certificate of thermometer SN#5616 used for room temperature has expired on 4/2022, the laboratory technical consultant confirmed on an interview on 1/6/2022 about 1:30pm.</p>
<p>D5437</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of calibration records for Beckman DXH800 and confirmed in an interview with the technical consultant on 10/6/2022 about 1:30pm, the laboratory failed to calibrate the hematology analyzer every six months in year 2020 through survey date. Approximately 6000 patients tested.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the review of API PT summary reports, the laboratory director failed to fulfill the laboratory director's responsibilities to ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the for the test analyte's Blood Urea Nitrogen (BUN), Troponin I, Vitamin D 25-OH, Free Testosterone, Mean Platelet Volume (MPV), and mean corpuscular volume (MCV). Refer to D6019.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the laboratory's API PT records and an interview with the technical consultant on 10/6/2022 about 1pm, the laboratory director failed to ensure that corrective action was performed and documented for the laboratory's unsatisfactory PT performance. Finding 1. Chemistry Miscellaneous second event 2020: Testosteron(Free) 67% 2. Immunology first event 2021 IgE 98% 3. Chemistry second event 2021 BNP 40%, 25-OH VitD 80%, Troponin I 40% 4. Chemistry third event 2021 BNP 0% 5. Chemistry first event 2022 Troponin I 80% 6. Hematology second event 2022 MCV 80%, MPV 80%

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on the review of laboratory's proficiencies testing records, policy and procedure manual, and calibration records, the laboratory director failed to maintain Quality Assurance program to ensure all aspects of laboratory testing. Refer: D5403, D5401, D6019, D6024, D5437, D5417, D5311

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's API PT records and confirmed in an interview with the technical consultant on 10/6/2022 1pm, the laboratory director failed to ensure that remedial action was taken and documented on two consecutive failed proficiency testing. Finding 1. Chemistry second event 2021 BNP 40% 2. Chemistry third event 2021 BNP 0%