

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2227488	(X3) Date Survey Completed 01/05/2023
Name of Provider or Supplier Brookhaven Heart Pllc	Street Address, City, State 915 Hillside Avenue, Suite C, New Hyde Park, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT reports, interview with the laboratory technical consultant on 1/5/2022 about 12:30pm, the laboratory did not evaluate and document corrective action for the PT scores less than 100% for the following analyte's: Chemistry 2022 2nd event cortisol 80%</p>
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's training/competency documentation, the laboratory failed to perform and maintain training/competency for technical consultant for 2021 and 2022. Confirmed on an interview with technical consultant on 01/05/2023 about 11:30am.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and</p>

test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on the review of humidity records and an interview with the technical consultant, the laboratory failed to follow the manufacturer's humidity requirement and the laboratory's humidity is out of range as per manufacturer. Finding: 1. The Tosoh G8 manufacturer humidity requirement is 40-80%. Laboratory humidity range was 20-80%. 2. 48 days out of manufacturer range between June-December 2021. 3. 81 days out of manufacturer range between January -December 2022 4. Confirmed on an interview with technical consultant on 1/5/2023 about 1:30pm

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on review of thermometer calibration expiration date, the laboratory failed to maintain calibration for following thermometers. It was confirmed on an interview with technical consultant on 01/05/2023 about 1pm. Finding: 1. SN# 42112 and SN# 18H13860932 expired September 2022. 2. SN# C2112540 No calibration.