Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1022919	02/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Heart Center Of The Oranges	5 Franklin Avenue, Belleville, NJ	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), External QA Summary Reports (EQASR) and interview with the General Supervisor (GS) the laboratory failed to verify the accuracy of Histopathology and Cytology testing from 5/2/24 to 2 /26/25. The findings include: 1. The laboratory failed to include physician agreement for the diagnosis of each case on the EQASR performed on 5/2/24. 2. The referring physician did not sign the EQASR from 5/2/24. 3. The GS confirmed on 2/26/25 at 1: 30 pm, the laboratory failed to verify the accuracy of Histopathology and Cytology testing.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS) the laboratory failed to establish corrective action procedures for the Biannual Assessment (BA) for Histopathology and Cytology tests from 9/7/23

	to 2/26/25. The finding includes: 1. The laboratory did not have a procedure if a disagreement occurred with the BA results and the corrective action taken if it occurred. 2. The GS confirmed on 2/26/25 at 1:45 pm the laboratory did not establish corrective action procedures for the BA.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 surveyor review of the Room Temperature/ Humidity Charts and interview with the General Supervisor (GS) the laboratory failed to document the temperature according to their defined criteria where Histopathology and Cytology tests were performed from 9/7/23 to 2/26/25. The findings include: 1. The defined acceptable temperature range was stated as 15C-25C on the Room Temperature/ Humidity charts. 2. Room temperature was incorrectly documented in degrees Fahrenheit and not in degrees Celsius. 3. The GS confirmed on 2/26/25 at 1:50 pm, room temperature was documented incorrectly on the Room Temperature/ Humidity charts.