Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1022919	(X3) Date Survey Completed 09/06/2023
Name of Provider or Supplier Heart Center Of The Oranges	**Street Address, City, State** 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
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 Laboratory Consultant (LC), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) on the date of survey. The findings include: 1. There was no BA procedure in the PM. 2. The LC confirmed on 9/6/23 at 12:15 pm that the laboratory did not have a BA procedure.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of Test Reports (TR), Electronic Medical Records (EMR) and interview with the Laboratory Consultant (LC), the laboratory failed to ensure that information from TR was manually transcribed accurately into the EMR for all tests on that date of survey. The LC confirmed on 9/6/23 at 11:15 am that the laboratory did not ensure information was manually transcribed accurately.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: A) Base on survey review of the Techincal Processing of the Specimen Report (TPSR) and interview with the Laboratory Consultant (LC) the laboratory failed to follow written policies and procedures for Specimen processing the findings include: 1. The TPSR stated "Slide preparation", "One Slide was stained with Diff Quick for adequacy evaluation". 2. The LC stated "we do not use or have Diff Quick" 3. The LC confirmed on 9/6/23 that the laboratory failed to follow the aforementioned procedure. B) Base on survey review of the TPSR and interview with the LC the laboratory failed to establish written policies and procedures for Specimen referral on the date of survey. The findings include: 1. The TPSR stated "More of the sample was then taken, to prepare another slide by cell block method. This was stained with H&E stain." 2. The LC stated "H&E staining is performed by a reference laboratory." 3. The LC confined on 9/6/23 at 11:40 am that the laboratory failed to establish written policies and procedures for Specimen referral.
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 surveyor review of the Procedure Manual (PM) and interview with the Laboratory Consultant (LC), the laboratory failed to follow their policy for "Centrifuges", "Microscopes", "Laboraotry Test Reports" and "Monitor Post-Analytical Key Indicators" on the date of survey. The findings include: 1. The PM stated under "Centrifuges", "The number of revolutions per minute (RPM) and the time of centrifugation must be checked annually". 2. The PM stated under "Microscopes" "All microscopes would be cleaned and aligned annually." 3. The PM stated under "Monitor Post-Analytical Key Indicators", "Indicators are monitor through the Laboratory Director an Medical Director monthly review of patient case results and resulting reports when necessary, average TAT, incidence reports and the annual review of patient filing system, computer SOP, and file and specimen storage capacity." 4. The PM stated under "Laboratory Test Reports" , "Final reports must (have): 5. date of receipt of specimen in the laboratory","7. Specimen source", " 5. There was no documented evidence that the aforementioned procedures were performed. 6. The LC confirmed on 9/6/23 at 12:30 pm that the laboratory failed to follow the aforementioned procedures.

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 surveyor review of the Procedure Manual (PM) and interview with the Laboraoty Consutnat (LC) the laboratory failed to have all applicable procedures for Histopathology and Cytology tests on the date of the survey. The finding includes: 1. Requirements for specimen collection, labeling, storage, transportation, processing, and referral. 2. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 3. The laboratory's system for entering results in the patient record and reporting patient results. 4. The LC confirmed on 9/6/23 at 10: 30 am that the laboratory did not have the above procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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 lack of Laboratory Temperature Logs (LTL) and interview with the Laboratory Consultant (LC), the laboratory failed to monitor and document Room temperature and humidity, where Histopathology, and Cytology tests are performed on the date of survey. The LC confirmed on 9/6/23 at 11:35 am that Room temperature and humidity were not documented .
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

	(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Laboratory Consultant (LC), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing on the date of survey. The findings include: 1. The laboratory did not document H&E stain QC reactions. 2. The laboratory read and reported approximately 5 patients each day of patient testing. 3. The LC confirmed on 9/6/23 at 11:30 am that the laboratory did not document H&E QC stain reactions.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, lack of laboratory records and interview with the Laboratory Consultant (LC) the laboratory Director (LD), failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology on the date of survey. Findings include: 1. The laboratory failed to provide written policies and procedures for an annual statistical evaluation of three required statistics for nongynecologic specimens. 2. The laboratory failed to provide an evaluation of three of three required statistics. Statistics include: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis to include unsatisfactory. 3. The LC confirmed on 9/6/23 at 11:00 am the laboratory did not have the above procedures.
D5667	CYTOLOGY CFR(s): 493.1274(h) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Base on the lack of Quality Control (QC) records and interview with the Laboratory Consultant (LC) the laboratory failed document all control procedures performed for Cytology testing at the time of survey. Approximately five patients where evaluated each day of patient testing. The LC confirmed at 11:30 am on 9/6/23 that the laboratory did not document all control procedures performed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) and interview with the Laboratory consultant (LC), the laboratory failed to ensure that the TR included all the required information on the date of survey. The findings include: 1. The TR did not have the name and address of the reference laboratory where Histopathology and Cytology slides where read. 2. The TR did not have the name and address of where the Techincal component for histopathology was performed. 3. The TR did not specify the name and address of where the Techincal component for cytology was performed. 4. The LC confirmed on 9/6//23 at 12:20 pm that the TR failed to include all the required information.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records, procedures and interview with the Laboratory Consultant (LC), the Laboratory Director (LD) failed to ensure that the laboratory maintained a QC program on the date of survey. The findings include: 1. There was no documented evidence that a control slide was observed on each day of patient testing for histopathology and cytology testing. 2. There was no documented evidence cytology statistics were being monitored. 3. There were no QC procedures for Cytology and Histopathlogy. 4. The LC confirmed on 9/6/23 at 12:00 pm the laboratory did not ensure a QC program was maintained.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Consultant (LC) , the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel at the time of survey. The LC confirmed on 9/6/23 at 10:00 am that a CA procedure was not established.