Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2090186	(X3) Date Survey Completed 06/13/2018
Name of Provider or Supplier Arkansas Heart Hospital Clinic - Conway	**Street Address, City, State** 605 Dave Ward, Suite 105, Conway, AR	

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
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: Through review of laboratory temperature records, observation, lack of documentation, and interview it was determined that the laboratory failed to employ any corrective action when cath lab procedure room refrigerator temperature was not monitored for three of five months in 2018. Findings follow: A. During an initial tour of the laboratory on 6/13/18 at approximately 09:15 AM a refrigerator with several laboratory supplies with storage temperature requirements was observed in the cath lab procedure room. B. Review of the laboratory's temperature records revealed that there was no record of the cath lab procedure room refrigerator temperature for January, February, or March, of 2018. C. In an interview on 6/13/18 at approximately 11:45 AM, the Laboratory Director identified as number 1 on the CMS 209 report, stated that temperatures are routinely monitored and recorded every 30 minutes via a wireless environmental monitoring system but the temperature for the cath lab procedure room refrigerator was not monitored during January 2018, February 2018, or March 2018 due to a system failure. D. Because access to the cath lab was unavailable at the time due to procedures being conducted, the Laboratory Director, identified as number 1 on the CMS 209 form, was asked what temperature dependent supplies were stored in the cath lab refrigerator and the Laboratory Director responded that ACT cuvettes with a storage requirement of 2 degrees C. to 8 degrees C., ACT

	liquid controls with a storage requirement of 2 degrees C. to 8 degrees C., I-Stat Chemistry controls with a storage requirement of 2 degrees C. to 8 degrees C., I-Stat EGC-6 cartidges with a storage requirement of 2 degrees C. to 8 degrees C. were currently stored in the refrigerator and were being stored in the refrigerator during the period of January through March of 2018. E. Upon request, the laboratory was unable to provide documentation of corrective action taken regarding the unavailability of cath lab procedure room refrigerator temperature monitoring during January through March of 2018. F. In an interview on 6/13/18 at approximately 1145, the laboratory director identified as number 1 on the CMS 209 form confirmed that the cath lab procedure room refrigerator temperature was not monitored in January through March of 2018 and no corrective actions were taken during the period in that regard.