Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0904608	(X3) Date Survey Completed 03/08/2018
Name of Provider or Supplier Conway Womens Health Center Pa	**Street Address, City, State** 2519 College Avenue, 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
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Through a review of the Becton-Dickinson (BD) Affirm package insert, temperature logs for 2016 and 2017, as well as interviews with staff, it was determined the laboratory failed to take corrective actions when the room temperature was out of range. As evidenced by: A. A review of the BD package insert for the Affirm test revealed "With each test run verify that the testing environment is 22-28 degrees Celsius (71.6-82.4 degrees Fahrenheit)." B. A review of the temperature logs for 2016 and 2017 revealed the Laboratory room temperature range as 22-28 degrees Celsius (71.6-82.4 degrees Fahrenheit). C. A review of the temperature logs from July-December 2016 revealed: In July 2016, the temperature was out of range 12 of 20 days: August 2016, 10 of 23 days: September 2016, 11 of 20 days: October 2016, 20 of 21 days: November 2016 12 of 20 days and in December 2016 3 of 20 days. The laboratory had no documentation of corrective actions performed on the days the room temperature was out of range. D. A review of the temperature logs from January-December 2017 revealed: In January 2017, the temperature was out of range 11 of 22 days: February 2017, 7 of 20 days: March 2017, 17 of 23 days: April 2017, 13 of 20 days: May 2017, 16 of 21 days: June 2017, 9 of 23 days: July 2017, 2 of 20 days: August 19 of 23 days: September 2017, 14 of 20 days: October 2017, 10 of 22 days: November 2017, six of 20 days and in December 2017, 5 of 20 days. The laboratory had no documentation of corrective actions performed on the days the room temperature was out of range. E. In an interview at 1047 on 3/8/2018, Laboratory personnel #2(as listed on form CMS-209) confirmed that no documented corrective action was taken to obtain optimal temperatures.