Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1051462	03/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Conway Hematology Oncology	350 Salem Rd, 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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of quality control policy and procedure "Quality Control Protocol", QC summary reports, lack of documentation, Cell Dyne Data Log and interview it was determined that the laboratory failed to document evaluation of patient results back to the last acceptable quality control result when quality control values fell outside of acceptable limits on one of one time when quality control for hemoglobin (Hgb) assay failed to meet criteria for acceptability in July 2018. . Findings follow: A. The quality control policy and procedure "Quality Control Protocol" for complete blood cell counts (CBC) states that quality control is unacceptable if either or both of the normal and./or abnormal controls fall outside of plus or minus 2 standard deviation range and if the control(s) are not acceptable after one rerun of the samples corrective action must be taken and documented and "if quality control is out of range due to a specific condition, once the condition is corrected the patients samples previously run must be checked for accuracy". B. Review of quality control records revealed that the Cell-Dyn LOWCTRL2 quality control (lot# 8130422) fell outside of acceptable range for Hgb assay on three succesive attempts on 7/24/18 with the following results: DATE TIME RESULTS ACCEPTABLE RANGE (5.5 to 6.1) 07/24 /18 0727 6.3 07/24/18 0731 6.2 07/24/18 0741 6.2 07/24/18 0750 6.1 (acceptable result) C. Review of quality control records revealed that the Cell-Dyn NORMCTRL2

	quality control (lot# 8130423) fell outside of acceptable range for Hgb assay on four succesive attempts on 7/24/18 with the following results: DATE TIME RESULTS ACCEPTABLE RANGE (11.7 to 12.7) 07/24/18 0728 12.9 07/24/18 0736 13.1 07/24 /18 0742 12.8 07/24/18 0751 12.8 07/24/18 1158 12.2 (acceptable result) D. Interview the technical consultant, identified as number three on the CMS 209 form, stated that corrective action consisted of calling the service representative to perform maintenance on the Cell Dyne CBC analyzer. E. Review of the quality control summary report revealed that the last successful CBC quality control for Hgb assay on the Cell Dyne analyzer was on 7/23/18 at 0734 F. Review of the "Cell Dyne Data Log" for 07/23/18 revealed that CBC results were performed and reported on twenty-two patients, identified as sequence numbers 9487, 9589, 9490, 9492, 9493, 9494, 9495, 9497 through 9500 inclusive, 9502 through 9507 inclusive, and 9509 through 9513 inclusive on 7/23/18 between 08:08 AM to 01:40 PM. G. Upon request, the laboratory was unable to provide documentation that the CBC results performed on the patients on 7/23/18 identified above had been evaluated. H. In an interview on 3/7 /19 at approximately 12:45 PM, the technical consultant, identified as number four on the CMS 209 form confirmed that the CBC results performed on 7/23/18 had not been evaluated.
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: Observation, review of laboratory temperature records, lack of documentation and interview revealed that the laboratory failed to employ corrective action when room temperature exceeded acceptable range in one of four laboratory rooms on five of seventeen days of operation in November 2018 and two of sixteen days of operation in December 2018. Findings follow: A. During an intial tour of the laboratory on 3/7 /19 at approximately 09:30 AM, four separate rooms in which supplies with storage temperature requirements were stored (laboratory #1, specimen collection area #1, laboratory #2, specimen collection area #2, and ancillary specimen collection #2) were observed in the facility. B. Review of laboratory temperature records revealed that room temperature in laboratory #1, with an acceptable range of 15 degrees Centigrade (C) to 25 degrees C., was recorded as 27 degrees C. on 11/19/18, 26 degrees C. on 11/21/18, 26 degrees C. on 11/26/18, 27 degrees C. on 11/27/18, 28 degrees C. on 11/28/18, 28 degrees C. on 12/5/18, and 27 degrees C. on 12/6/18. C. During a tour of the laboratory on 3/7/18 at approximately 12:30 PM, 600 ea. 4.5 ml. BD EDTA blood collection tubes lot# 8303685 expiration date 2020-03-31 with a storage temperature requirement of 5 degrees C. to 25 degrees C.; 200 4.5 ml. BD heparin blood collection tubes lot # 8187745 expiration date 2019-07-31 with a storage temperature requirement of 5 degrees C. to 25 degrees C; 200 ea. 5.0 ml. BD serum separator blood collection tubes expiration date 2019-11-30 with a storage temperature requirement of 5 degrees C. to 25 degrees C; 200 ea. 4.5 ml. BD Na Citrate blood collection tubes lot # 8156595 expiration date 2019/03/31 with a storage temperature requirement of 5 degrees C. to 25 degrees C. were observed in the laboratory #1 room. D. Upon request, the laboratory could not provide documentation of corrective action taken when room temperature exceeded acceptable range in laboratory room #1 on the dates identified above. E. In an interview on 3/7/18 at

	approximately 12:45 PM, the technical consultant, identified as number three on the CMS 209 form, and testing personnel, identified as number four on the CMS 209 form, confirmed that the laboratory had not taken any corrective action when laboratory room temperature exceeded acceptable range on the events identified above.