Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0901317	12/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Conway Medical Group- Conway Regional	437 Dennison, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Through review of Lab Quality Assessment: Quarterly Review reports dated January - March 2023, laboratory daily log sheet, quality control reports, lack of documentation and interview it was determined that the laboratory failed to retain quality control records or background check records for the Pochi Hematology analyzer. Findings follow: A) Review of the Quality Assurance Notes for 2023 revealed the following comments: 1) On the quarterly January - March report "excessive backgrounds on Pochi". 2) On the quarterly April - June report "Pochi out for one month" B) Review of the daily log dated October 23, 2023 revealed "sending Pochi out due to QC issues with various levels". C) Review of daily background counts for March, July and November 2023 revealed no instance when background counts were unacceptable. D) Review of QC results for March, July and November 2023 revealed no instance of quality control results failing to meet criteria for acceptability however no QC results were presented for November 1, 2023 through November 15, 2023. E) In an interview on 12/12/23 at 11:35 a.m., the laboratory staff member (#2 on the CMS 209 form) was asked if records of all QC result reports, including those which were unacceptable, and records of unacceptable background reports on the Pochi analyzer were retained. She stated that print-outs of unacceptable QC and background counts were discarded and were only kept for two weeks in the data files of the Pochi analyzer after that period there was no record.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Through review of the CMS 209 form, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to assess employee competency as directed in personnel requirements. Survey findings follow: A) Review of the CMS 209 form submitted by the laboratory revealed that the laboratory staff member (#2 on the CMS 209 form) was listed as the technical consultant. B) Review of personnel records for laboratory staff member (# 2 on the CMS 209 form) revealed that no competency evaluation for the position of technical consultant was present for calendar year 2023. B) Upon request, the laboratory was unable to provide documentation of competency determinations for calendar year 2023 for the position of technical consultant for the personnel identified above. C) In an interview at 1:31 p. m. on December 12, 2023 the health system staff member (# 2 on the Entrance/Exit Conference Attendance Record) confirmed that competency determinations have not been performed on the personnel designated as technical consultant and that she had served as technical consultant for the full year of 2023.
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 laboratory policy and procedure, quality control (QC) summary reports for complete blood counts (CBC), lack of documentation and interview with laboratory staff members it was determined that the laboratory failed to document corrective action taken on one of one occasions when quality control results failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory policy and procedure for QC revealed that corrective action is to be documented when QC results fail to meet criteria for acceptability. B) Review of the QC summary for October 2023 revealed on October 21, 2023 Eightcheck - 3WP Xtra hematology QC material lot number 32490711 with an acceptable range (35.9 - 41.3) was resulted 42.1 at 4:02 p.m., 41.9 at 4:30 p.m. and 42.4 at 5:45 p.m., all outside the acceptable range. C) Upon request, the laboratory was unable to provide documentation of the corrective action taken by the laboratory. D) In an interview on 12/12/23 at 1:17 p.m., the laboratory staff member (#2 on the CMS 209 form) confirmed that corrective action was not documented on the occasion identified above.