

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0467525	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Central Arkansas Pediatric Clinic	Street Address, City, State 2301 Springhill Road, Suite 200, Benton, 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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Through review of the laboratory's Policy and Procedure for Quality Control, "Quality Control Results" report, the "Remedial (Corrective) Action Log", the Medonic M-Series User's Manual, lack of documentation and interview it was determined that the laboratory failed to document corrective action when quality control failed to meet the laboratory's criteria for acceptability on one of one occasion in July 2017 and seven of seven occasions in November 2017, and the laboratory failed to document corrective action when the precision of analytes failed to meet the manufacturer's defined parameters on two of thirteen analytes in July of 2017, and three of thirteen analytes in November of 2017. Findings follow: A. The laboratory failed to document corrective action when quality control results failed to meet the laboratory's criteria for acceptability. 1. The laboratory's policy for quality control requires corrective action to be documented when any analyte remains outside of acceptable limits on a second attempt. 2. Review of the laboratory's "Quality Control Results" report revealed that on July 5, 2017 the normal level Boule hematology control (lot number 217055 N) with an acceptable range for hemoglobin of (11.2 to 11.6) was recorded as 12.1 at 07:31, 12.1 at 07:35, and 12.1 at 07:38. 3. Review of the laboratory's</p>

"Remedial (Corrective) Action Log for July 5, 2017 revealed an entry of "Normal fail X 3 Hgb. 12.1 X 3 attempts". 4. Review of the laboratory's "Quality Control Results" report revealed that on July 14, 2017 the normal level Boule hematology control (lot number 217055 N) with an acceptable range for hemoglobin of (11.2 to 11.6) was recorded as 12.9 at 17:10, 13.3 at 17:13, 12.5 at 17:15 and 15.7 at 17:17 and the normal level Boule hematology control (lot number 217055 N) with an acceptable range for RBC of 3.85 to 4.03 was recorded as 4.48 at 17:10, 4.55 at 17:13, 4.35 at 17:15 and 5.54 at 17:17. 5. Review of the laboratory's "Remedial (Corrective) Action Log for July 2017 revealed no entry of corrective action for July 14, 2017. 6. Review of the laboratory's "Quality Control Results" report revealed that on July 24, 2017 the normal level Boule hematology control (lot number 217055 N) with an acceptable range for hemoglobin of (11.2 to 11.6) was recorded as 12.1 at 07:39, 12.1 at 07:45, and 11.7 at 08:06. 7. Review of the laboratory's "Remedial (Corrective) Action Log for July 2017 revealed no entry of corrective action for July 24, 2017. 8. Review of the laboratory's "Quality Control Results" report revealed that on July 28, 2017 the normal level Boule hematology control (lot number 217055 N) with an acceptable range for hemoglobin of (11.2 to 11.6) was recorded as 12.9 at 07:41, and 12.2 at 07:48. 9. Review of the laboratory's "Remedial (Corrective) Action Log for July 2017 revealed no entry of corrective action for July 28, 2017. 10. Review of the laboratory's "Quality Control Results" report revealed that on July 3, 2017 the high level Boule hematology control (lot number 217055 H) with an acceptable range for hemoglobin of (14.0 to 15.0) was recorded as 15.4 at 07:16, and 15.2 at 07:32. 11. Review of the laboratory's "Remedial (Corrective) Action Log for July 2017 revealed no entry of corrective action for July 3, 2017. 12. Review of the laboratory's "Quality Control Results" report revealed that on July 13, 2017 the high level Boule hematology control (lot number 217055 H) with an acceptable range for hemoglobin of (14.0 to 15.0) was recorded as 13.3 at 07:34, 15.3 at 07:38, and 15.7 at 07:45 and the high level Boule hematology control (lot number 217055 H) with an acceptable range for RBC of 4.44 to 4.88 was recorded as 4.25 at 07:34, 4.84 at 07:38, and 4.95 at 07:45 . 13. Review of the laboratory's "Remedial (Corrective) Action Log for July 2017 revealed no entry of corrective action for July 13, 2017. 14. Review of the laboratory's "Quality Control Results" report revealed that on July 28, 2017 the high level Boule hematology control (lot number 217055 H) with an acceptable range for hemoglobin of (14.0 to 15.0) was recorded as 15.9 at 07:19, and 16.1 at 07:32, and the high level Boule hematology control (lot number 217055 H) with an acceptable range for RBC of 4.44 to 4.88 was recorded as 5.18 at 07:19, and 5.20 at 07:32., 15. Review of the laboratory's "Remedial (Corrective) Action Log for July 2017 revealed no entry of corrective action for July 28, 2017. 16. Review of the laboratory's "Quality Control Results" report revealed that on November 18, 2017 the normal level Boule hematology control (lot number 217085 N) with an acceptable range for hemoglobin of (10.9 to 11.7) was recorded as 12.0 at 08:30, 12.7 at 08:48 ,and 12.0 at 08:54 and the normal level Boule hematology control (lot number 217085 N) with an acceptable range for RBC of 3.73 to 4.09 was recorded as 4.14 at 08:30, 4.39 at 08:48, and 4.10 at 08:54 . 17. Review of the laboratory's "Remedial (Corrective) Action Log for November 2017 revealed no entry of corrective action for November 18, 2017. 18. In an interview on June 7, 2018 at approximately 1200, the technical consultant identified as number 2 on the CMS 209 form confirmed that documentation of corrective action was required and was not present on the events identified above. B. The laboratory failed to document corrective action when the laboratory's precision failed to meet the instrument manufacturer's parameters. 1. Review of the Medonics M-Series user's manual revealed the following published expected coefficient of variation parameter ranges for reproducibility: * RBC less than or equal to 1.5% * Hemoglobin less than or equal to 1.3% * WBC less than or equal to 2.5%. 2. Review

of the laboratory's quality control report for July 2017 revealed that the coefficient of variation experienced by the laboratory for Boule normal control (lot number 217055 N) was 2.3% for hemoglobin, the coefficient of variation experienced by the laboratory for Boule high control (lot number 217055 H) was 2.7% for RBC and 2.5% for hemoglobin. 3 .Review of the laboratory's quality control report for November 2017 revealed that the coefficient of variation experienced by the laboratory for Boule normal control (lot number 217085 N) was 3.3% for hemoglobin, 4.0% for WBC, and 3.5% for RBC, and the coefficient of variation experienced by the laboratory for Boule high control (lot number 2170585 H) was 4.2% for RBC, 5.4% for WBC, and 4.0% for hemoglobin. 4. In an interview on June 7, 2018 at approximately 1200, the technical consultant identified as number 2 on the CMS 209 form confirmed that the precision for hematology analytes experienced by the laboratory was unacceptable and that there was no corrective action documented.