

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466177	(X3) Date Survey Completed 01/19/2021
Name of Provider or Supplier Baptist Health Family Clinic Bryant	Street Address, City, State 4411 Hwy 5 North, Bryant, 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	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</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 "Temp Form /Daily QC Log", the "All Sample Report", 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 November 2020. Findings follow: A) 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. B) Review of the laboratory's "Quality Control Results" report revealed no instance of quality control failures. C) Review of the laboratory's Temp Form/Daily QC Log for November 2020 revealed low level control failed on five attempts for WBC on 11/20/20 . D) Review of the laboratory's "All Sample Report" for the Medonic Hematology analyzer revealed that Boule Con-Diff Hematology low level control, lot # 2200821 with an acceptable range for WBC of 3.1 to 3.7 was recorded as 3.0, 3.0, 3.0, 2.9, and 1.3 before an acceptable result of 3.2 on 11/20/20. E) Review of the laboratory's "Remedial (Corrective) Action Log" for November 2020 revealed no entry of corrective action for any date in November 2020. F) In an interview with the laboratory staff member, identified as number two on the CMS 209 report, confirmed that in the instance identified above the quality</p>

control results were unacceptable and that the corrective action taken should have been documented.