

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0889073	(X3) Date Survey Completed 03/10/2021
Name of Provider or Supplier Boston Mountain Rural Health Center,Inc-Huntsville	Street Address, City, State 934 North Gaskill Street, Huntsville, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Through a review of the "Leadcare II Users Guide", the "Lead Quality Control Log", lack of documentation, and interviews with laboratory staff, it was determined, the laboratory failed to follow the Leadcare II manufacturer's instructions for troubleshooting quality control failures. Survey findings include: A. The Leadcare II Users Guide states, "You must run both the Level 1 and Level 2 controls to verify the performance of the system." It further stated, "When testing controls, make sure that the value falls within the acceptable range for each control. Do NOT proceed to patient samples if the control results are outside acceptable limits." B. A review of the "Lead Quality Control Log" revealed that on 6/1/2020 High Control (lot # 1925M) results were not documented on the Lead Quality Control Log but were documented on the Kit Assay Sheet as 20.6, 20.7, and 24.5 (acceptable range 28.7 to 36.7). An acceptable quality control result for High Control was not documented until 6/8/2020. C. Three patients (#1, #2, and #3 from the eClinical Works Labs/Di/Proc. document) had Lead results documented on 6/1/2020 when quality control was not within acceptable range. D. In an interview, at 10:36 on 3/10/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed three patients were reported on 6/1/2020, when quality control was not acceptable.</p>