

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465446	(X3) Date Survey Completed 03/15/2019
Name of Provider or Supplier Bradley County Medical Center	Street Address, City, State 404 South Bradley Street, Warren, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the manufacturer's instructions for the analyte Lactic Acid (LA), patient medical records, lack of documentation as well as interviews with staff, it was determined the laboratory failed to ensure the optimum integrity of patient specimens from the time of collection and receipt of the specimen through completion of testing and reporting of results. As evidenced by: A. A review of manufacturer's instructions for Lactic Acid revealed "Specimens for Lactic Acid analysis must be centrifuged and separated within fifteen minutes and analyzed immediately. If the test cannot be performed immediately, refrigerate the separate plasma for up to 24 hours or freeze specimen up to 30 days." B. A review of Lactic Acid patient results for February and March (two of three months) of 2019 revealed three of fifty-one patient results were not performed according to manufacturer' instructions. Patient #651335 Lactic acid collected at 1851 completed at 2035; Patient #6519329 Lactic acid collected at 0700 completed at 0805 and patient #653060 Lactic acid collected at 2336 completed 0040. C. Upon request the laboratory could not provide documentation that the specimens had been refrigerated or frozen for future analysis. D. In an interview at 1030 on 3/14/2019, the general supervisor (as listed on form CMS 209) confirmed the laboratory did not analyzed the specimens immediately.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p>

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Through a review of the Blood Bank policy and procedure manual, Helmer Plasma Thawer maintenance log for 2018, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to ensure function checks for the Helmer Plasma Thawer were within laboratory's established guidelines before patient testing: As evidenced by: A. A review of the Blood Bank policy and procedure manual revealed the maintenance protocol for the Helmer Plasma Thawer: "Quarterly function checks should be performed for the alarm and the lubrication of the rail." B. A review of the maintenance log for Helmer Plasma Thawer for January-December of 2018 revealed the quarterly function checks were not performed in four of four quarters for 2018. C. In an interview on 03/15/2019 at 11:30, general supervisor (as listed on the form CMS-209) confirmed the function checks were not performed for four of four quarters in 2018.