

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2135841	(X3) Date Survey Completed 02/12/2020
Name of Provider or Supplier Sark-Opl	Street Address, City, State 7200 South Hazel Street, Pine Bluff, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Through a review of laboratory policy and procedure manual, A review of Abbott I-stat user manual, temperature logs for 2019, lack of documentation, and interviews with staff, it was determined the laboratory failed to document room and refrigerator temperatures as well as humidity conditions that are essential for the operation of Abbott I-Stat analyzer and the proper storage of quality controls and reagents. Survey findings follow: A. A review of the policy and procedure manual revealed the policy for daily temperature checks. "It is the policy of this office to ensure the conditions that are essential for the proper storage of reagents and testing of patient sample are met and documented daily. The temperatures will be taken daily by testing personnel using a calibrated thermometer. The results will be recorded on the Temperature /Humidity Monthly log form." B. A review of the Abbott I-Stat User manual revealed the specifications for the analyzer: Operating Temperature 16-30 degrees Celsius; Relative Humidity 0-95%. C. A review of the Laboratory temperature logs revealed the ranges for Room Temperature 16-25 degrees Celsius; Refrigerator 2-8 degrees Celsius and Humidity as 0-90%. D. A review of the Daily Temperature logs for January-December 2019 (12 of 12 months) revealed the laboratory failed to document temperatures: In February 2019; nine of twenty days: in March 2019; sixteen of twenty-one days: in April 2019; twenty of twenty-two days; in May 2019 nineteen of</p>

twenty-three days; in June twenty-one of twenty-two days; in August nine of twenty-one days and in November 2019 thirty of thirty days. E. In an interview at 10:30 on 2/12/2020 the technical consultant confirmed the lack of documented temperatures.