Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2135841	04/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sark-Opl	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
D0000	. This is the initial survey of the laboratory conducted on 4/17/2018. At the time of the initial survey the laboratory was not in compliance with the following conditions: 493.1215 Hematology 493.1403 Moderate Complexity Laboratory Director 493.1421 Laboratory Testing Personnel
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Through a review of policy and procedure manual, ACT patient logs, lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to meet requirements for Hematology. As evidenced by: 5413: the laboratory failed to monitor and document temperatures. 5545: the laboratory failed to document quantitative controls for Activated Clotting Time when patients were tested.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on review of the laboratory's personnel records, policy and procedure manual as well as interview with staff, it was determine the laboratory failed to have written

	procedures to completely assess competency. As evidenced by: A. A review of the policy and procedure manual revealed the laboratory did not have a written procedure to assess competency using all six methods of assessment. B. In an interview on 4/17 /2018 at 10:30, laboratory personnel #2 (as listed on CMS-209) confirmed that the laboratory failed to have documentation that all six methods of assessment were used to determine competency assessment.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Through a review of patient testing logs, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to verify the accuracy of Activated Clotting Time testing at least twice annually as evidenced by: A. A review of patient testing logs revealed the laboratory uses the Abbott I-stat to perform Activated Clotting Times. B. A review of ACT patient testing logs revealed the laboratory started patient testing December 2017. C. The surveyor requested documentation for verifying the accuracy of ACT testing none was provided. There was no documentation that the laboratory had enrolled in a CMS approved proficiency testing program. D. In an interview with facility administrator on 4/17/2018 at 1030, confirmed the laboratory has not enrolled in a proficiency testing program.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: . 1. Through a review of the laboratory policy and procedure manual, lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to define acceptable criteria for temperature as evidenced by: A. A review of the policy and procedure manual revealed the laboratory failed to define acceptable criteria for room temperature, refrigerator temperature and humidity conditions. B. In an interview at 11:00 on 4/17/2018, laboratory personal #2 (as listed on form CMS 209) stated that there is no acceptable range developed for any of the temperatures monitored. 2. Through a review of the Abbott I-Stat instrument manual ,observations made during a tour of laboratory, lack of documentation as well as interviews with staff, it was determined the laboratory failed to monitor and document room temperature, refrigerator temperature and humidity conditions that are essential for proper storage of supplies as evidenced by: A. A review of the Abbot I-Stat instrument manual revealed the operating temperature of the analyzer as 16-30 degree Celsius (61-86 degree Fahrenheit) and the relative humidity as less than or equal to

	90%. B. During a tour of the laboratory on 4/17/2018 at 11:30, the following were observed in the refrigerator: one box of Abbott I-Stat cartridges (storage temperature 2-8 degrees Celsius), one box of quality controls (Level-II lot #271092 expiration date 8/31/2018) for Activated Clotting Time test (storage temperature 2-8 degrees Celsius). C. The surveyor requested documentation for daily room temperature, refrigerator temperature and humidity conditions. None was provided. D. In an interview on 4/17 /2018 at 11:45, laboratory personnel #2 (as listed on form CMS 209) confirmed the laboratory failed to monitor and document temperatures since December 2017.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Through a review of Activated Clotting Time (ACT) patient test logs, lack of documentation, as well as interview with staff, it was determined the laboratory failed to perform quality controls (QC) each day patient specimens were analyzed. Not performing Quality Controls has the potential of affecting all patients tested. As evidenced by: A. A review of ACT patient logs for February-April of 2018 revealed the laboratory performed thirteen ACT tests. B. The surveyor requested QC records for February-April 2018 when patients were tested. None was provided. C. ACT patient test logs include the following patients (as identified on the patient identification worksheet) tested from February-April 2018 when no QC was performed: patient #0120747, patient #011153, patient #091264, patient #020528, patient #072947, patient #030148, patient #011748, patient #072245, patient #090161, patient #012438, patient #011255 and patient #061350. D. In an interview on 4/17 /2018 at 10:30, laboratory personnel #2 (as listed on form CMS 209) confirmed patients were analyzed without performing quality controls.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Through a review of personnel records, patient test logs, lack of documentation as well as interviews with staff, it was determined the laboratory director failed to provide overall management and direction as cited at: 6020: the laboratory director failed to ensure the quality control program was established and maintained 6032: the laboratory director failed to auathorize testing personnel to perform moderate complexity testing without supervision 6063: the laboratory director failed to ensure testing personnel had documentation of appropriate education
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Through a review of policy and procedure manual, patient testing logs, lack of documentation as well as interview with staff, it was determined the laboratory director failed to ensure the quality control program is established and maintained as cited at: 5545: the laboratory failed to perform quality control for Activated Clotting Time test eight hours patient specimens were assayed.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of Laboratory personnel files, lack of documentation, and interviews with staff, it was determined the Laboratory Director failed to specify, in writing, which examinations and procedures each individual is authorized to perform and whether supervision is required. As evidence by: A. Personnel records for one of one testing personnel (as listed on the form CMS-209) failed to include the Laboratory Director's written authorization to perform moderate complexity testing. B. In an interview at 11:00, on 04/17/2018, laboratory employee # 2 (as listed on the form CMS-209) confirmed there were no written authorizations from the Laboratory Director stating the tests that each individual is authorized to perform.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Through a review of personnel files for one of one laboratory employees (listed on the form CMS-209), through a lack of documentation, and through interviews with

	staff, it was determined that laboratory testing personnel lacked documentation of appropriate education to qualify as testing personnel for moderate complexity testing. As cited at: D6065: testing personnel qualifications
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Through a review of personnel records for one of one laboratory employees (as listed on the form CMS-209), through a lack of documentation, and through interviews with staff, it was determined that Laboratory testing personnel lacked documentation of appropriate education to qualify as moderate complexity testing personnel. As evidenced by: A. A review of personnel records revealed no documentation of appropriate education was available for laboratory personnel, #2 (as listed on the form CMS-209). B. In an interview at 09:30 on 04/17/2018, laboratory personnel #2 (as listed on the form CMS-209) confirmed the lack of documentation of appropriate education for one of one testing personnel.