Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461318	07/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Abrom Kaplan Memorial Hospital	1310 West 7th Street, Kaplan, LA	

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	A Recertification Survey was performed June 28, 2021 through July 1, 2021 at Abrom Kaplan Memorial Hospital, CLIA ID # 19D0461318. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of policy and procedure manual revealed the laboratory did not include the following: a) Laboratory Information System (LIS) validation procedure and frequency of performance 2. In interview on July 1, 2021 at 4:03 pm, Personnel 2 stated the laboratory does not perform LIS validations. Personnel 2 confirmed the laboratory's policy manual did not include the identified procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on observation, review of laboratory's Normal Mean Prothrombin Time (NMPT) records, donor questionnaires and interview with personnel, the laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Findings: 1. Observation by surveyor during the laboratory tour on June 28, 2021 at 1:30 pm revealed the laboratory utilizes the Siemens Sysmex CA-600 series analyzer for Prothrombin Time (PT) testing. 2. Review of the laboratory's NMPT study revealed the laboratory utilizes the "Verification of Interval (Normal Patient Population)" questionnaire for acceptable normal donor samples to include the following: a) Are you on any medication? (Including aspirin, Birth Control, Estrogen, or Hormone Therapy) _____ Yes _____ No b) Are you in good Health? (ie., No pathological conditions, No pre surgical or hospitalized patient) _____ Yes _____ No 3. Further review of the NMPT records and donor questionnaires revealed the laboratory utilized the following three (3) of forty (40) donors who did not meet the acceptable criteria: a) RT 20-289-1950: documented "NO" for Are you in good health? b) RT 20-293-2052: documented "NO" for Are you in good health? c) RT 20-289-1908: documented "NO" for Are you in good health? 4. In interview on June 30, 2021 at 3:25 pm, Personnel 2 stated that Personnel 3 handles the NMPT study and did not know why non-acceptable donors were used for the study. Personnel 2 confirmed the laboratory used the identified unacceptable donors for the NMPT study. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 1,082 PT/INR tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the laboratory's Blood Bank Quality Control log, patient records and interview with personnel, the laboratory failed to ensure that Blood Bank reagents were not used beyond their expiration dates. Findings: 1. Review of the laboratory's Blood Bank Quality Control (QC) log from January 2020 through June 2021 revealed the laboratory documented the use of expired reagents for the following one (1) of five hundred forty seven (547) days reviewed: a) On July 3, 2020 at 13:00 pm, the laboratory documented the use of MQC-neg (Lot #2006051QG 2/4) with the expiration date of July 2, 2020. b) On July 3, 2020 at 13:00 pm, the laboratory documented the use of MQC-pos (Lot #2006051QG 1/3) with the expiration date of July 2, 2020. 2. Review of patient records from January 2020 through June 2021 revealed the laboratory did not perform any patient testing on July 3, 2020. 2. In interview on July 1, 2021 at 1:15 pm, Personnel 2 stated the testing personnel did not document the correct lot and expiration date for the change from old Blood Bank QC lot to the new Blood Bank QC lot. Personnel 2 confirmed the laboratory documented the use of expired QC for the identified date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's performance verification studies and package inserts along with interview with personnel, the laboratory failed to have complete studies for Direct Bilirubin neonatal population. Findings: 1. Observation by surveyor during the laboratory tour on June 28, 2021 at 1:00 pm revealed the laboratory utilizes the Abbott Alinity c analyzer for Direct Bilirubin testing. 2. Review of the Abbott Alinity c package insert for Direct Bilirubin revealed "Abbott Laboratories has not verified the assay performance characteristics with neonatal specimens". 3. In interview on June 29, 2021 at 2:42 pm, Personnel 2 stated the laboratory did not have a pediatric doctor on staff and neonatal specimens are not routinely performed except through emergency room testing. 4. Review of the laboratory's performance verification studies for Direct Bilirubin revealed the laboratory did not perform complete studies for the neonatal population to include accuracy, complete precision, reportable range and reference range. 5. In interview on June 29, 2021 at 2:42 pm, Personnel 2 confirmed the laboratory did not perform Direct Bilirubin performance studies for neonatal specimens.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the laboratory's Blood Bank Maintenance logs and corrective action log as well as interview with personnel, the laboratory failed to perform the quarterly Blood Bank alarm check when identified by corrective action and Quality Assurance (QA) checks. Findings: 1. Review of the laboratory's 2020 Blood Bank Maintenance logs revealed the laboratory did not perform the quarterly Blood Bank alarm check for January 2020; however, the laboratory did identify the alarm check was not performed as required by documenting to see the corrective action log. 2. Review of the laboratory's corrective action log for February 2020 revealed the laboratory documented the quarterly alarm temperature check was not performed and that there was no spikes seen throughout the month. 3. Further review of the corrective action log for February 2020 revealed the laboratory documented that alarm check was good in October 2019 and that personnel would check the Blood Bank alarm in April 2020

	as scheduled. 4. In interview on July 1, 2021 at 1:15 pm, Personnel 1 confirmed the laboratory did not perform the Blood Bank alarm check when identfied by QA.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Refer to D5411. 3. The laboratory failed to ensure that Blood Bank reagents were not used beyond their expiration dates. Refer to D5417. 4. The laboratory failed to have complete studies for Direct Bilirubin neonatal population. Refer to D5421. 5. The laboratory failed to perform the quarterly Blood Bank alarm check when identified by corrective action and Quality Assurance (QA) checks. Refer to D5781.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Refer to D5411. 2. The laboratory failed to ensure that Blood Bank reagents were not used beyond their expiration dates. Refer to D5417.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Refer to D5411. 3. The laboratory failed to ensure that Blood Bank reagents were not used beyond their expiration dates. Refer to D5417.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.