Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642286	04/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nea Baptist Clinic - Main Laboratory	4802 E Johnson Ave, Jonesboro, 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	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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation of one of four rooms in which supplies with storage temperature requirements were stored Findings follow: A) During a tour of the laboratory on 3/13 /23 at 08:45 a.m. four separate rooms containing items with a temperature storage requirement; #1 the main laboratory, #2 storage/break room, #3 the Women's Clinic and #4 Women's Clinic storage room were observed. B) During a review of the laboratory's temperature records it was noted that temperature records for room #3, the storage/break room was not presented. C) During a tour of the laboratory on 4/14 /23 at 01:20 p.m. 15 cases of 1,000 BD EDTA blood collection tubes lot# 2200107 expiration date 2023-11-30, 15 cases of 1,000 BD EDTA blood collection tubes lot # 2227125, and 3000 BD Gel Heparin blood collection tubes lot # 2292111 all with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed in room #3 the storage/break room D) Upon request, the laboratory could not present the temperature records for the storage/break room #3 in which the supplies identified above were stored,. F) In an interview on 4/14/23 at 1:20 p.m. the laboratory staff

	member (number 4 on the CMS 209 form) confirmed that the daily temperature of the room, in which the supplies identified above were stored, had not been monitored and recorded.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through review of package inserts, observation, and interview it was determined that the laboratory did not change expiration dates on control materials after opening as required by manufacturer. Finding follow: A) Review of the package insert for Coulter 6C Hematology controls revealed that the product expires in 16 days after vial is opened and put into use and the expiration dates should be changed as required after opening. B) During a tour of the laboratory on 4/14/23 at 10:00 a.m.the surveyor observed a plastic container with three vials of Coulter 6C hematology controls , lot #'s 123175150, 133284140 and 143194150 . The vials did not have new expiration dates or dates put into use indicated on the testing materials or the container and were identified as the controls currently in use. C) In an interview on 4/14/23 at 10:50 a.m. laboratory staff member (number 6 on form CMS 209) confirmed that no amended expiration date or date when put into use were written on the vials or container.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of the laboratory's QC Protocol, prothrombin time (PT) and partial thromboplastin time (PTT) quality control (QC) summary reports for March and November 2022, QC summary reports for prostatic specific antigen (PSA) tests for September 2022, corrective action documentation, patient result reports and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results since the last successful QC performance in three of three occasions when corrective action to correct QC failures required a change in the testing system. Findings follow: 1) QC failure for PT testing in March 2022 A) Review of the laboratory's "QC Protocol" revealed on page 3, paragraph "g". the protocol states "if QC was out of range due to a specific condition, once the condition is corrected the patient samples previously run must be checked for accuracy". B) Review of QC results for PT testing on March 30, 2022 revealed that the abnormal STA Control Abn

	plus lot # 258020 was out of accptable range (+ 2 standard deviations (SD)) on four successive attempts at 09:10 a.m., 09:20 a.m., 09:56 a.m., and 10:02 a.m. until being acceptable at 10:39 a.m.. C) Review of the corrective action documentation revealed the statement "reran QC for abnormal PT still out, made fresh abnormal control and reran QC still out, made fresh neoplastin reran QC good". The change to fresh reagent represented a change in the test system. D) Review of the QC summary for PT testing revealed that the last acceptable QC for PT testing prior to 9/30/22 at 10:39 a.m. was performed at 9/29/22 at 12:32 p.m. E) Review of patient results for PT testing revealed that 2 patients (10380372, 10463788) had PT test results performed between 9/29/22 at 12:32 p.m. and 9/30/22 at 10:39 a.m.. 2) QC failure for PTT testing in November 2022 A) Review of QC results for PTT testing on November 10, 2022 revealed that the STA Control N Plus lot # 260332 was out of acceptable range (+ 2 SD) on two succesive attempts at 07:59 a.m and 08:17 a.m. and STA Control Abn Plus was out of acceptable range on two succesive attempts at 08:00 a.m., 08:18 a.m., until both were acceptable at 08:52 a.m.. B) Review of the corrective action documentation revealed the statement "made new PTT reagent all good"". The change to fresh reagent represented a change in the test system. C) Review of the QC summary for PTT testing revealed that the last acceptable QC for PTT testing prior to 11/10/22 at 08:52 was performed at 11/9/22 at 09:00 a.m D) Review of patient results for PTT testing revealed that 4 patients (10184669, 10387838, 10434210, 10459597) had PTT test results performed between 11/9/22 at 09:00 a.m. and 11/10/22 at 08:52 a. m. 3) QC failure for PSA testing in September 2022 A) Review of QC results for PSA testing on September 28 , 2022 revealed that the Biorad Normal Control lot # 85271 was out of acceptable range (+ 2 SD) at 08:15 a.m and the Biorad abnormal control lot # 85272 was out of acceptable range at 08:11 a.m.., until both were acceptable at 10: 11 a.m.. B) Review of the corrective action documentation revealed the statement "PSA out, changed reagent pack and got a new bottle of QC, QC good"". The change to fresh reagent represented a change in the test system. C) Review of the QC summary for PSA testing revealed that the last acceptable QC for PSA testing prior to 9/28/22 at 10:11 a.m. was performed on 9/26/22 at 07:30 a.m D) Review of patient results for PSA testing revealed that 23 patients (identified as numbers 1 through 23 on a separate patient identification list) had PSA test results performed between 9/26 /22 at 07:30 a.m. and 9/28/22 at 10:11 a.m. E) In an interview on 4/13/23 at 2:52 p.m., the laboratory staff member (# 4 on the CMS 209 form) confirmed the results on the occasions identified above had not been evaluated and should have been according to protocol.