Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0683904	11/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nea Baptist Clinic Windover	1111 Windover, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Through review of API Hematology proficiency testing reports for 2020 and 2021, original laboratory documentation for handling, preparation, processing, examination, and each step in the testing and reporting of results for proficiency testing samples, laboratory policy and procedure and interview it was determined that in one of five API hematology proficiency testing events in 2021 the laboratory failed to test proficiency testing samples in the same manner as patient testing by testing two of five specimens twice when patient specimens would not have been tested twice . Findings follow. A) Review of laboratory original result print outs of specimens HSY06, HSY07, HSY08, HSY09, HSY10 in the second API proficiency testing event of 2021 revealed that all the specimens were tested twice, B) Review of the laboratory policy and procedure revealed that hematology results which exceed critical values or which have instrument flags should be retested. C) Review of the results of the proficiency testing event, identified above, revealed that specimens HSY 06, and HSY 10 did not have results which, by laboratory policy and procedure, would require testing to be repeated. D. In an interview on 11/3/21 at 02:45 PM the laboratory staff

	member, identified as number two on the CMS 209 form, confirmed that proficiency testing samples, identified above, were not tested in the same manner as patient testing.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 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. This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for specimen identification, observation and interview it was determined that the laboratory failed to identify one of thirteen observed urine specimens using unique identifiers. Findings follow: A. Review of the laboratory's policy and procedure for specimen identification revealed that all specimens are to be identified with the patient's first and last names and date of birth. B. During a tour of the laboratory on 11/3/21 at 4:45 PM the surveyor observed one of thirteen urine specimens in the laboratory sink labeled with the patient's first and last name only C. In an interview on 11/3/21 at 4:45 PM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the specimen observed in the sink was labeled with the patient's first and last name only.
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, manufacturer's instrument manuals, review of temperature and humidity records for 2020 and 2021, lack of documentation and interview it was determined that the room humidity was below that required for the Sysmex XP300 instrument utilized by the laboratory for the performance of complete blood counts (CBC) in one of 24 months reviewed and room humidity acceptable range did not conform to the manufacturer's requirement for Sysmex XP300 hematology analyzer. Findings follow: A) During an initial tour of the laboratory at 01:00 PM on 11/3/21 a Sysmex XP300 CBC analyzer was observed in the main laboratory room. B) Review of manufacturer's instrument manuals revealed an operating humidity range required for the Sysmex XP300 hematology analyzer of 30% to 85% . C) Review of room temperature and humidity records for 2020 and 2021 revealed that the room humidity acceptable range in the main laboratory, in which the Sysmex XP300 is operated, was defined as 15% to 85% and records documented that the actual humidity was less than 30% on 2/14/21 through 2/21/21. D) Upon request the laboratory was unable to

	provide documentation of corrective action when humidity was less than required in the main laboratory for the months identified. E) In an interview on 11/3/21 at 04:30 PM the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the humidity in the main lab room was below that required on the occasions identified above and the humidity acceptable range identified in temperature records did not conform to the manufacturer's requirement.
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: Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 11/3/21 at 04:30 PM eight of fourteen BD Na Citrate blood collection tubes lot 363083 expiration date 2021-8-31 were observed on two phlebotomy trays and six of sixteen Hologic Aptima Multitest Swab Specimen Collection Kits lot 265730A expiration date 2021-06-30 were observed in laboratory cabinets. B) In an interview on 11/3/21 at 04:30 PM the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that the items, identified above, had exceeded their expiration dates and were available for use.