Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642286	10/06/2021
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
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: . Through a review of the new instrument validation, which was performed on 08/20/2021 for the Vitros 7600 Chemistry analyzer, as well as interviews with staff, it was determined the laboratory failed to validate the reportable range established by the manufacturer for five of twenty-five Chemistry tests validated on the Vitros 7600. Survey Findings follow: A. A review of the Analytical Range Verification for Amylase (AMYL) on the Vitros 7600 revealed analytical range listed on the documentation as 30-1200 the laboratory only documented verification to 893.3; the analytical range verification for Alkaline Phosphatase (ALKP) on the Vitros 7600 listed on the documentation as 20-1500 the laboratory only documented verification to 1185.05; the analytical range verification for Total Bilirubin (TBIL) on the Vitros 7600 listed on the documentation as 0.1-27 the laboratory only documented verification to 17.93; the analytical range verification for Direct Low-Density Lipoprotein (dLDL) on the Vitros 7600 listed on the documentation as 30-350 the laboratory only documented verification to 117.02 and the analytical range verification for Creatine Kinase (CK) on the Vitros 7600 listed on the documentation as 20-1600 the laboratory only documented verification to 1471.1. B. The surveyor requested documentation for verification of the full analytical range of the listed analytes. None was provided. C. In an interview at 10:00 on 10/6/2021, the laboratory

	director confirmed the laboratory did not validate the full reportable range for CK, AMYL, TBIL, dLDL and ALKP claimed by the manufacturer of the Vitros 7600.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of policy and procedure manual, quality control (QC) records for 2021, patient medical records, lack of documentation as well as interviews with staff, it was determined that patients were reported when results of quality control failed to meet the laboratory's criteria for acceptability. Survey findings follow: A. A review of the policy and procedure manual revealed the protocol for Chemistry QC: "Two levels of quality control will be run each day of patient testing. Patient will not be report until QC is acceptable." B. A review of chemistry quality control results for March and August of 2021 (two of eight months), revealed on 8/3/2021 Performance Verifier Level 1 was out of range for Glucose, Urea and Uric Acid with no documentation of an acceptable quality control results for Performance Verifier Level 1. C. A review of medical records revealed on 8/03/2021 the laboratory reported 160 Comprehensive Metabolic Panels with only one level of control in range for Glucose, Urea and Uric Acid. D. In an interview on 10/06/2021 at 10:00, laboratory director confirmed that patients were reported when the quality control results were outside of the laboratory's acceptable range.