

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1005851	(X3) Date Survey Completed 08/18/2021
Name of Provider or Supplier Nea Baptist Clinic - Hilltop	Street Address, City, State 4901 East Johnson Avenue, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through observation, manufacturer's instrument manuals, review of temperature and humidity records for 2021 and 2020, lack of documentation and interview it was determined that the room humidity was below that required by instruments utilized by the laboratory for the performance of complete blood counts (CBC) in seven of twelve months reviewed and room humidity was not monitored in one of two rooms in which instruments with an operating humidity requirement were used for testing. Findings follow: A) During an initial tour of the laboratory at 08:30 AM on 8/18/21 a Sysmex 1000i CBC analyzer was observed in the main laboratory room and a DCA Vantage analyzer, used for performing A1C Hemoglobin analyses, was observed in a room separated from the main laboratory by a closable door. B) Review of manufacturer's instrument manuals revealed an operating humidity range required for the Sysmex 1000i hematology analyzer of 30% to 85% and an operating humidity range required for the DCA Vantage analyzer of 10% to 90%. 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 1000i is operated, was defined as 20% to 75% and records documented that the actual humidity was less than 30% in three of thirty-one days in October 2020, fifteen of thirty days in November 2020, thirty-one of thirty-one days in December 2020, thirty-one of thirty-one days in January 2021,</p>

twenty-eight of twenty-eight days in February 2021, twenty-seven of thirty-one days in March 2021, twenty-six of thirty days in April 2021, and four of thirty-one days in May 2021. 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 above or to provide documentation of the humidity in the room in which the DCA Vantage analyzer was operated. E) In an interview on 8/18/21 at 12:30 PM the laboratory staff member, identified as number three 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 in the room in which the DCA Vantage analyzer was operated had not been documented.