

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0682130	<b>(X3) Date Survey Completed</b>  01/05/2022
<b>Name of Provider or Supplier</b>  St Bernards Medical Center - Carson Street	<b>Street Address, City, State</b>  300 Carson Street, Jonesboro, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Through review of the DCA Vantage Analyzer Operator's Guide (2008) Revision B, DCA Systems Hemoglobin A1C Reagent Kit Package Insert, review of laboratory's policy and procedure for A1C hemoglobin, observation, lack of documentation and interview it was determined that the laboratory failed to follow manufacturer's instructions for performing external quality control (QC) by each new user of the system and failed to amend expiration dates for test kits when stored at room temperature. Findings follow: A) Review of the DCA Vantage Analyzer Operator's Guide (2008) Revision B revealed that "two levels of QC is to be performed with each new shipment, each new lot number, and each new operator". B) Review of the DCA Systems Hemoglobin A1C Reagent Kit Package Insert revealed that reagents maintain their published expiration date if stored at 2 degrees C. to 8 degrees C. and the expiration date is reduced to 90 days if stored at room temperature. C) Review of the laboratory's policy procedure for A1C Hemoglobin assays performed on the DCA Vantage analyzer revealed instructions to "date cartridge box when placed in room temperature". D) During a tour of the laboratory on 1/5/22 at 10:00 AM, two of two boxes of DCA systems Reagent Cartridges Lot # 0877091 expiration date 23-09-30 were observed at room temperature in the testing area of the Endocrinology clinic with no date marked on the boxes of when they were placed at room temperature. E) Upon request, the laboratory was unable to provide documentation that two levels of QC were performed by each new operator. F) In an interview on 1/5/21 at 10:35 AM , the laboratory staff member, identified as number three on the CMS 209 form, said that the laboratory personnel perform all QC and the test operators in the</p>

Endocrinology clinic do not perform QC and confirmed that the DCA Vantage test cartridges were not labeled when they were placed at room temperature and there was no documentation of QC performed by new operators in the Endocrinology clinic.