

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D1067996	(X3) Date Survey Completed 11/06/2025
Name of Provider or Supplier Doctors Now Walk In Care Johnston	Street Address, City, State 8779 Northpark Court Suite 100, Johnston, IA	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) 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:</p> <p>A. Based on observations made during the survey, review of test system manufacturer's instructions and confirmed by interview with the clinic manager /compliance officer at approximately 1:00 pm on 11/6/2025, the laboratory failed to retain the manufacturer's instructions for one out of 11 test systems. The findings include: 1. The laboratory did not have the manufacturer's instructions for the Afinion 2 hemoglobin A1C test system. 2. At the time of the survey, the clinic manager /compliance officer confirmed the lack of manufacturer's instructions for the Afinion 2 hemoglobin A1C test system. B. Based on observations made during the survey, review of test system manufacturer's instructions and confirmed by interview with the clinic manager/compliance officer at approximately 1:00 pm on 11/6/2025, the laboratory failed to follow the manufacturer's storage requirements for 11 out of 11 test systems. The findings include: 1. Observations made during the survey revealed the laboratory had in use the following waived test systems: Sofia 2 influenza A/B, Sofia 2 influenza + SARS antigen, Sofia 2 Streptococcus A, OSMO infectious mononucleosis, QuickVue COVID antigen, Assure Platinum blood glucose, Aimstrip hemoglobin, Consult diagnostics 10 SG urine dipstick, QuickVue urine human chorionic gonadotropin (hCG), Piccolo Express, and Afinion 2 hemoglobin A1C. 2. The manufacturer's instructions state the Sofia 2 influenza A/B, Sofia 2 influenza + SARS antigen, Sofia 2 Streptococcus A, OSMO infectious mononucleosis, QuickVue COVID antigen, Aimstrip hemoglobin, and QuickVue hCG test kits need to be stored between 59 degrees Fahrenheit and 86 degrees Fahrenheit. 3. The manufacturer's instructions state the Assure Platinum blood glucose and Consult diagnostics 10 SG</p>

urine dipsticks need to be stored between 35 degrees Fahrenheit and 86 degrees Fahrenheit. 4. The manufacturer's instructions state the Piccolo Express test cartridges must be stored in the refrigerator between 36 degrees Fahrenheit and 46 degrees Fahrenheit. 5. The laboratory did not have the manufacturer's instructions available for the Afinion 2 hemoglobin A1C test system to verify storage requirements. See D1001A. 6. At the time of the survey, the clinic manager/compliance officer confirmed the laboratory failed to document daily the room temperature and refrigerator temperature where the above test kits are stored and in use.