

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2028939	<b>(X3) Date Survey Completed</b>  11/06/2025
<b>Name of Provider or Supplier</b>  Doctors Now Walk-In Care West Des Moines	<b>Street Address, City, State</b>  640 S 50th Street, Suite 1100, West Des Moines, IA	
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>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 1:50 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 1:50 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. C. 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 1:50 pm on 11/6/2025, the laboratory failed to follow the manufacturer's expiration date requirements for two out of 11 test systems. The findings include: 1. The manufacturer's instructions for both the Consult diagnostics 10 SG urine dipstick and Aimstrip hemoglobin analyzer stated that test strips expire three months after opening. 2. Observations made during the survey revealed the laboratory had in use lot number URS5030147 of Consult diagnostics 10 SG urine dipstick and lot number Hb4040014 of hemoglobin test strips (used with the Aimstrip hemoglobin analyzer). 3. The laboratory failed to document the open date for lot number URS5030147 of Consult diagnostics 10 SG urine dipstick and lot number Hb4040014 of hemoglobin test strips (used with the Aimstrip hemoglobin analyzer). Therefore, the expiration date of each lot number of test strips could not be determined. 4. At the time of the survey, the clinic manager/compliance officer confirmed the laboratory failed to document the open date for both lot numbers of test strips. D. 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 1:50 pm on 11/6/2025, the laboratory failed to follow the manufacturer's quality control (QC) requirements for one out of one lot number of glucometer test strips used on 11/6/2025. The findings include: 1. The manufacturer's instructions for the Assure Platinum Blood glucose system stated two levels of QC must be performed with each new bottle of glucometer test strips. 2. Observations made during the survey revealed the laboratory had opened lot number 6341650 of Assure Platinum blood glucose test strips on 11/4/2025. 3. During the survey, the laboratory performed patient glucose testing using lot number 6341650 of Assure Platinum blood glucose test strips. 4. During the survey, the clinic manager /compliance officer tried to perform two levels of QC for lot number 6341650 of Assure Platinum blood glucose test strips but could not get level 2 QC to fall within the manufacturer's established QC ranges. 5. At the time of the survey, the clinic manager/compliance officer confirmed the laboratory failed to perform two levels of QC for lot number 6341650 of Assure Platinum blood glucose test strips.