Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D1100107	11/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Now Walk In Care Altoona	3770 Eighth Street Sw, Altoona, 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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: 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 10:30 am 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 10:30 am 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

	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 patient logs, and confirmed by interview with the clinic manager /compliance officer at approximately 10:30 am on 11/6/2025, the laboratory failed to follow the manufacturer's expiration date requirements for three out of 11 test systems. The findings include: 1. The manufacturer's instructions for the Consult diagnostics 10 SG urine dipstick, Aimstrip hemoglobin analyzer, and the Assure Platinum blood glucose test system stated that test strips expire three months after opening. 2. Observations made during the survey revealed the laboratory had in use lot number URS4120012 of Consult diagnostics 10 SG urine dipstick and lot number Hb4040014 of hemoglobin test strips (used with the Aimstrip hemoglobin analyzer). 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. 3. Observations made during the survey revealed the laboratory had in use lot number 633705U of Assure Platinum glucose test strips. The laboratory recorded the open date of the test strips as 3/31/2025, meaning the test strips expired on 6/30/2025. On 10/31/2025 the laboratory performed patient glucose testing using lot number 6341650 of Assure Platinum blood glucose test strips. 4. At the time of the survey, the clinic manager /compliance officer confirmed the laboratory failed to document the open date for Consult diagnostics 10 SG urine dipstick and hemoglobin test strips. In addition, the clinic manager/compliance officer confirmed the Assure Platinum glucose test strips exceeded their expiration date. D. Based on observations made during the survey; review of test system manufacturer's instructions, quality control logs, and patient test logs; and confirmed by interview with the clinic manager/compliance officer at approximately 10:30 am 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. The findings include: 1. The manufacturer's instructions for the Assure Platinum Blood glucose system stated two levels of QC must be performed and within the established ranges for 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 3/31/2025. 3. On 3/31/2025 the laboratory performed two levels of QC. However, the laboratory accepted a QC result of 355 mg/dL which fell outside of the manufacturer's established level 2 QC range of 202 - 252 mg/dL. 4. On 10/31/2025 the laboratory performed patient glucose testing using lot number 6341650 of Assure Platinum blood glucose test strips. 5. At the time of the survey, the clinic manager/compliance office confirmed the laboratory did not follow the manufacturer's QC requirements.