

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2129650	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Quick Care Clinic	Street Address, City, State 1420 4th Street Se, Mason City, 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>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 lack of manufacturer's instructions and confirmed by the laboratory owner at approximately 10:30 am on 7/12/2018, the laboratory failed to retain the manufacturer's instructions for the following test systems: Henry Schein One Step + influenza A/B, Henry Schein One Step + mononucleosis, Henry Schein One Step + urine pregnancy, and Piccolo chemistry analyzer. At the time of the survey, the laboratory did not have the manufacturer's instructions for the previously named test systems. B. Based on the True Track operator's guide and observations made during the survey at approximately 10:45 am on 7/12/2018, the laboratory failed to document the in use date for one out of two bottles of True Track glucometer test strips (lot number RT 5053, expiration date 5/31/2019). The findings include: 1. The operator's guide for the True Track glucometer states, "Test strips expire 120 days after opening or the expiration date, whichever comes first." 2. At the time of the survey, the laboratory had one open bottle of True Track glucometer test strips (lot number RT 5053, expiration date 5/31/2019). The laboratory did not document the open date of the glucometer test strips.</p>