

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0984477	(X3) Date Survey Completed 02/15/2018
Name of Provider or Supplier Roosevelt Co Hospital District	Street Address, City, State 42121 Us Hwy 70, Portales, NM	
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
D0000	The following deficiencies were cited during a recertification survey completed on 02/15/2018 for the federal requirements of 42 CFR Part 493 for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, the review of manufacturer's instructions, temperature records and interviews with laboratory staff, the laboratory failed to ensure the environmental conditions in the laboratory met the manufacturer's requirements for the TOSOH G8 immunochemistry analyzer and the Clinitek Advantus urine analyzer. Findings are: Observation of the laboratory on 2/15/18 at 2:40 pm revealed one vent blowing air directly on the TOSOH immunochemistry analyzer. The air flow from the vent was strong enough to cause the instrument tape to visibly move in the breeze. The vent was located approximately 3 feet from the open doorway to the phlebotomy room and 6-8 feet from the Advantus urine analyzer. 1. The manufacturer of the TOSOH analyzer stated in the Operator's Manual to not install the unit in the path of direct air currents. 2. Review of the Advantus manufacturer's instructions indicated the ambient operating temperature should be 18 - 30 degrees Celsius. The instructions also indicate "At temperatures under 22 degrees Celsius, urobilinogen and leukocyte results may be decreased, and at temperatures above 26 degrees Celsius, increased." 3. Review of the Siemens Multistix 10 SG package insert indicated the following</p>

limitations for Urobilinogen, "Strip reactivity increases with temperature; the optimum temperature is 22-26 degrees Celsius." 4. Review of room temperature records for the phlebotomy room (connected through an open doorway near the vent) and the blood bank/serology area (closest to the Advantus) revealed the laboratory did not have the correct acceptable range for the operation of the Clinitek Advantus urine analyzer. The laboratory's temperature logs indicated the acceptable range was 15 - 25 degrees Celsius. The laboratory recorded the temperature twice per day. 5. Review of the temperature records indicated that the temperature was less than 18 degrees Celsius for the initial temperature recorded for each day. a. Blood Bank Serology area 8 of 31 days in July 2017 3 of 30 days in November 2017 23 of 31 days in December 2017 b. Phlebotomy area 8 of 30 days in June 2017 13 of 31 days in July 2017 2 of 31 days in August 2017 6 of 30 days in September 2017 15 of 31 days in October 2017 28 of 30 days in November 2017 14 of 31 days in December 2017 6. During the exit conference on 2/15/18 at 4:30 pm, the laboratory director, laboratory manager and the clinic administrator acknowledged these findings.