Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	32D0714232	02/28/2019

Name of Provider or Supplier	Street Address, City, State
Guadalupe County Hospital	117 Camino De Vida, Santa Rosa, 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 as the result of a recertification survey completed on 02/28/2019 for 42 CFR part 493 Laboratory Requirements.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on the review of manufacturer's instructions, temperature/humidity records, observation, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's humidity requirements for the operation of the hematology analyzer. Findings are: A. Review of the manufacturer's instructions for the Sysmex 1000i hematology analyzer and laboratory temperature/humidity logs revealed that the laboratory failed to follow manufacturer instructions for an acceptable humidity range of 30 - 80 % humidity. The log indicated an acceptable range of 15-75%. The humidity was below 30% for: 1. 31 of 31 days in January 2017. 2. 30 of 30 days in April 2017. 3. 8 of 30 days in June 2017. 4. 1 of 30 days in September 2017. B. Review of the laboratory's temperature and humidity logs revealed the laboratory failed to perform and document corrective actions when the humidity failed to meet the laboratory's acceptable humidity range of 15-75%. The humidity was below 15% for: 1. 9 of 31 days in January 2017, 2. 1 of 30 days in June 2017, 3. 22 of 30 days in January 2018, 4. 15 of 30 days in April 2018, 5. 15 of 31 days in December 2018. C. On 02/27/19 at 4:34 pm, during an interview, the Laboratory Manager stated the

	laboratory's humidifier did not seem to make much of a difference in the humidity and was not currently in use. D. On 02/27/19 at 4:10 pm, during observation of the hygrometer (a device used for measuring humidity), the reading indicated the humidity level was 12%.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of installation/validation records for the Siemens Dimension EXL 200 Chemistry analyzer, laboratory policy and interview with the laboratory manager, the laboratory failed to perform run-to-run precision studies during the installation of the analyzer. Findings are: A. Review of the Siemens Dimension EXL 200 Chemistry validation studies revealed no documentation of run-to-run precision studies. The installation records indicated the Siemens technical representative did the installation 02/16-02/25/18 and the actual printouts and studies were dated 02/19/18. B. During interview on 02/27/19 at 2:24 pm, the laboratory manager stated that the precision study was conducted on 1 day only by the technical representative. On 02/27/19 at 4:34 pm, the laboratory manager stated that he had spoken to the Siemens technical representative and confirmed that he had only performed a simple or within-run precision study. C. Review of the undated laboratory policy titled, "Method Evaluation" indicated the following requirements: "1. Split Sample Correlation - Run 20 samples on the present - reference method as well as the new method. 2. Within - Run precision - Run the sample 20 times within the same run on the new method. 3. Run to Run Precision and operator variance- A. Obtain specimens to test for a given analyte with sufficient volume to assay a minimum of 20 times over a minimum of four days. B. Ideally, the concentrations of the precision samples should represent various concentrations along the measuring range. Quality Control material works very well for this procedure. C. Different operators of the new method to determine operator variance should perform the runs."