Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0482451	11/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Collom & Carney Clinical Lab	2931 Richmond Rd, Texarkana, TX	

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 facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
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 surveyor observation, review of the laboratory environmental logs, and confirmed in interview, the laboratory failed to store quality control materials as required by the manufacturer for forty-nine days of the three months reviewed. 1. At 11:00 hours on 11/30/2021 in the laboratory storage area, the surveyor observed the following quality control materials stored in the 'Reagent Freezer': Bio-Rad Liquid Unassayed Multiqual Levels 1, 2 and 3. With a storage requirement of -20(degrees) Celsius to -70(degrees) Celsius. 2. Based on review of the laboratory's environmental logs for March, May, and June 2021 the following fourty-nine days were recorded outside the required temperature range of -20(degrees) Celsius to -70(degrees) Celsius. March 2021: 23 Days 3/1/2021: -18 3/2/2021: -18 3/3/2021: -18 3/4/2021: -18 3/5/2021: -19 3/6/2021: -18 3/7/2021: -19 3/8/2021: -19 3/9/2021: -19 3/10/2021: -19 3/11/2021: -18 3/12/2021: -18 3/13/2021: -19 3/14/2021: -18 3/15/2021: -16 3/16 /2021: -18 3/17/2021: -18 3/18/2021: -19 3/19/2021: -19 3/21/2021: -19 3/25/2021: -19 3/26/2021: -19 3/28/2021: -19 May 2021: 15 Days 5/2/2021: -19 5/5/2021: -19 5/8 /2021: -19 5/10/2021: -19 5/19/2021: -19 5/15/2021: -19 5/16/2021: -18 5/17/2021:

	-18 5/18/2021: -16 5/19/2021: -18 5/20/2021: -19 5/21/2021: -19 5/22/2021: -19 5/24 /2021: -19 5/25/2021: -19 June 20211: 11 Days 6/1/2021: -19 6/12/2021: -19 6/13 /2021: -19 6/14/2021: -19 6/21/2021: -19 6/23/2021: -19 6/24/2021: -19 6/25/2021: -19 6/26/2021: -19 6/27/2021: -19 6/30/2021: -19 3. Interview at 12:23 hours on 11/30 /2021 with the primary testing person confirmed that the laboratory failed to have a freezer that provided a consistent temperature range less than -20(degrees) Celsius for the storage of the Bio-Rad quality controls. .
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of laboratory policies and procedures, quality control (QC) records, and interview with facility personnel, the laboratory failed to define the QC standard deviations as required by their laboratory policy for three of three levels of QC used to monitor assay performance on the Beckman/Coulter DxC 600 Chemistry analyzer. 1. Review of the laboratory procedure with the purpose 'to establish standardized procedures for the quality control used in the Chemistry department' section 'Quality Control', subsection 'NEW LOT OF QUALITY CONTROL:' stated the following: "When receiving a new lot of quality control, the new lot level 1, 2, and 3 must be run in conjunction with the old lot for about 30 days. 1. Enter in new lot number to the computer of the DxC using the suggested mean of the package insert accessed on www.qcnet.com. 2. Use the SD that is historical for the initial setting for the new QC. 3. Once the 30 runs are complete, the new mean and SD is calculated by the DxC and can be adjusted at that time. 4. A new lot of QC is set in the BioRad software located in www.qcnet.com. Enter both the old lot QC values and the new lot values in qcnet. A statistical report will be available on or about the 16th of the month for evaluation. 5. The report features SDI and CVI, helping with the accuracy and precision determinations, ensuring the values of the new lot are performing as designed and within specifications." 2. Review of the laboratory QC summary printouts in comparison to the DxC 600 Chemistry analyzer QC assigned values list the following SD values for three of three BioRad QC in use: BioRad QC 56682: Analyte-QC Summary-Assigned SD(DxC) ALB 0.07 0.6 ALP 4.6 10 ALT 2 3 AMY7 2.3 4 AST 1.7 2.7 BUN 0.6 1 CALC 0.21 0.8 CL 1.2 1.8 CO2 0.9 1.3 CR-S 0.063 0.3 DBIL 0.05 0.1 GULm 2.8 3.5 K 0.06 0.08 NA 1.4 2.5 TBILI 0.17 0.25 TP 0.11 0.3 URIC 0.09 0.2 BioRad QC 56681 Analyte-QC Summary-Assigned SD(DxC) ALB 0.03 0.8 ALP 2 4 ALT 0.9 3 AMY7 1 3 AST 0.8 3 BUN 0.4 2 CALC 0.14 0.5 CL 0.9 1.5 CO2 0.9 1.5 CR-S 0.035 0.15 DBIL 0.04 0.1 GULm 2.1 4 K 0.08 0.2 NA 1.3 1.6 TBILI 0.1 0.5 TP 0.06 0.5 URIC 0.08 0.5 BioRad QC 56683 Analyte-QC Summary-Assigned SD

	(DxC) ALB 0.09 0.2 ALP 10.5 13 ALT 3.1 4.2 AMY7 6.2 8 AST 6.8 7 BUN 1.1 2 CALC 0.27 0.8 CL 1.6 2.5 CO2 1 2 CR-S 0.208 0.3 DBIL 0.4 0.2 GULm 6.1 7 K 0.1 0.7 NA 1.6 2 TBILI 0.35 0.4 TP 0.2 0.3 URIC 0.15 0.3 3. In an interview at 14:20 hours on 11/30/2021 the primary testing person stated that the SD for the new lot QC sometimes came from the establishment of the 30 run with the old lot, or sometimes it came from the peer review data, and they weren't always good at keeping up with the adjustments. .