Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0489140	02/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Center Of Ozona	102 North Ave H, Ozona, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions 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 observation, review of manufacturer's instructions, and interview, the laboratory failed to store Bio-Rad Liquichek Diabetes Control material in a non frost-free freezer for one of one freezer. Findings follow. A. During a tour of the laboratory on February 14, 2023, at 1450 hours, the surveyor observed Bio-Rad Liquichek Diabetes Controls in a Frigidaire frost-free freezer: 1. One unopened box of each Lot 55771 and 55772, 6 x 1 mL, 2. One opened box of each Lot 55771 and 55772, 3 x 1 mL. B. Review of the package insert for the Bio-Rad Liquichek Diabetes Control, 07 /2022 5250-00, under Storage and Stability stated, "This product will be stable until the expiration date when stored unopened at -10 to -70 degrees Celsius. Thawed Unopened: When thawed and stored unopened at 2 to 8 degrees Celsius, this product will be stable as follows: - All analytes: 6 months Make a note of the date when storage at 2 to 8 degrees Celsius begins. Do not use past expiration date. Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: - All analytes: 14 days Once thawed, do not

	refreeze this product. Discard the remaining material. This product is shipped under frozen conditions." C. Interview with Technical Consultant #2, as listed on the CMS form 209, on February 15, 2023, at 1330 hours in the laboratory confirmed the freezer was a frost-free freezer, and agreed, the freezer goes through freeze thaw cycles to prevent ice buildup.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, calibration verification, and interview, the laboratory failed to assess failures in linearity using the Roche Cobas Integra 400 Plus analyzer for two of two events reviewed. Findings follow. A. Review of the Maine Standards Validate GC1 Calibration Verification/Linearity Test Kit, 05-000211-07/05-200585-00, under Calculation of Results stated, "After theoretical values are calculated, for each analyte plot the expected (Theoretical) value or the x-axis versus the Recovered value on the y-axis using standard linear graph paper. If the system is linear, the plot should approximate a straight line. The point at which the line is no longer straight can be used to determine the limit of linearity or the reportable range. Data reduction is available from LGC Maine Standards. Commercially available linear regression software may also be used. The software should provide data point display and x-y graphical presentation. Linear regression should be interpreted using standard statistical analysis and the results should be compared with the instrument manufacturer's claims for linearity or with individual laboratory performance requirements. The degree of acceptable nonlinearity is an individual judgement based on methodology, clinical significance and medical decision levels of the test analyte." B. Review of calibration verification reports from August 2022 showed 6 out of 22 failures in linearity: Date Analyte Vial % diff % Limit 1. 08/19/22 Na 5 2.0 1.6 2. 08/19/22 Cl 2 2.8 2.5 3. 08/19/22 Ca 4 5.2 4.2 5 6.0 4.2 4. 08/19/22 Crea 4 11.3 7.5 5 13.1 7.5 5. 08/19/22 Alb 5 9.2 5 6. 08/19/22 TP 5 6.2 5 Review of calibration verification reports from February 2022 showed 4 out of 22 failures in linearity: Date Analyte Vial % diff % Limit 1. 02/10/22 Cl 5 2.8 2.5 2. 02/10/22 Crea 4 10.2 7.5 5 11.5 7.5 3. 02/10/22 Alb 5 6.5 5 4. 02/10/22 TP 5 6.0 5 C. Interview with the Laboratory Director acknowledged after speaking with technical support for the product, that failures should be evaluated based on the allowable error, peer data, clinical significance, or trends in quality control. KEY: Na = Sodium Cl = Chloride Ca = Calcium Crea = Creatinine Alb = Albumin TP = Total Protein
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of reference materials and interview, the laboratory failed to provide photomicrographs of sediment for performing microscopic urinalysis for two of two years reviewed. Findings follow. A. Photomicrographs for urine sediment were requested on February 15, 2023, at 1520 hours but not provided. B. Interview with Technical Consultant #2, as listed on the CMS form 209, on February 15, 2023, at 1520 hours acknowledged she used google to search for unknown sediment and did not have reference material in the laboratory.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, interview, review of the laboratory's corrective action log, and LIS query, the laboratory failed to evaluate all patient test results to the last acceptable QC (Quality Control) for QC failures using the Roche Cobas Integra 400 Plus analyzer that could not be resolved with repeat testing for five out of five QC failures documented from August 2022 to February 2023. Findings follow. A. Surveyor observed on February 14, 2023, at 1715 hours in the laboratory a rack of SST tubes sitting on the counter. B. Interview with Technical Consultant #2 on February 14, 2023, at 1715 hours acknowledged the tubes were samples run in the morning [and throughout the day] that they throw out the next morning. When asked how they would remediate patient testing if they had instrument problems the following day, responded they don't do that and stated there was no room in the refrigerator to store samples. C. Review of the laboratory's Roche Cobas Integra corrective action log from 08/26/2022 - 02/15/2023 showed the following calibrations, maintenance, or service as corrective action to QC failures: Date Test Problem Corrective Action 02/15 /23 Cl Level 2 out of range Calibrated 02/14/23 Cl Level 1 & 2 out of range Calibrated 02/13/23 Cl Level 2 out of range Calibrated 02/10/23 Cl Level 2 out of range Calibrated 02/08/23 Cl Level 2 out of range Calibrated 02/02/23 Cl Level 1 & 2 out of range Calibrated 02/01/23 Cl Level 2 out of range Replaced electrode, service 01/30/23 Ca Level 1 & 2 out of range Calibrated 01/23/23 Cl, K, Na Level 2 out of range Calibrated 01/18/23 Ca, Crea Level 2 out of range Calibrated 01/13/23 BUN Level 2 out of range Calibrated 01/13/23 Cl, K, Na Level 2 out of range Calibrated 12

	/20/22 Crea Level 1 out of range Calibrated 12/20/22 BUN Level 2 out of range Calibrated 12/16/22 Na, K Level 1 out of range Calibrated 12/16/22 Cl, BUN, Glu Level 2 out of range Calibrated 12/07/22 Uric Level 2 out of range Calibrated 11/18 /22 Crea Level 1 out of range Calibrated 11/04/22 Crea Level 1 out of range Calibrated 11/04/22 Cl, K, Na, Phos Level 2 out of range Calibrated 10/24/22 Ca Level 1 & 2 out of range Calibrated 10/20/22 Crea Level 1 out of range Calibrated 10 /19/22 Crea Level 1 out of range Calibrated 10/07/22 Cl Level 2 out of range Calibrated 09/20/22 Mg Level 1 & 2 out of range Calibrated 09/13/22 Chol Level 1 & 2 out of range Calibrated 09/06/22 BUN Level 2 out of range Calibrated 08/26/22 Alb Level 1 & 2 out of range Calibrated D. Random review of a query of the LIS showed: on 01/31/23 2 Cl tests were performed; on 1/28/22 0 Ca tests were performed, on 1/27 /22 7 Ca tests were performed; on 12/19/22 9 Crea/BUN tests were performed; on 10 /22/22 0 Ca tests were performed, on 10/21/22 7 Ca tests were performed; on 08/03 /22 6 Cl tests were performed. KEY: SST = Serum Separator Tube Na = Sodium K = Potassium Cl = Chloride BUN = Blood Urea Nitrogen Crea = Creatinine Glu = Glucose Uric = Uric Acid Phos = Phosphorus Mg = Magnesium Chol = Cholesterol