Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0489140	04/02/2025
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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policy and procedure, quality control (QC) records, laboratory records, interview, and pre-survey paperwork, the laboratory failed to follow their own procedure for establishing

	standard deviation (SD) for their BioRad Lyphochek Assayed Chemistry Control tested on the Roche Cobas Integra chemistry analyzer for three of three months reviewed. Findings follow. A. Review of the BioRad Lyphochek Assayed Chemistry Control, 06/2023, under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product... It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." The values in the Assignment of Values Data Charts are +/- 3SD ranges requiring the laboratory to establish its own mean and ranges. B. Review of the laboratory's policy and procedure titled Internal Quality Control, revised 02/26/2025, stated, "Controls must be within the established 2 standard deviation acceptable range before patient testing can be performed. Before using new lot number of controls, 20 repetitive runs will be performed to calculate the mean and establish the 2SD range for each analyte." C. Review of the Roche Cobas Integra QC reports from 10/01/2024 - 12/31/2024 were reviewed against the laboratory established means and ranges shown on the Westgard QC Online QC Calculator records for each analyte. The following discrepancies were observed listed by analyte, Level 1/2 (L1/L2), established 1SD, established 2SD, 2SD setting in analyzer (some equivalent to 4SD). Alb: L1/ 0.1/ 0.2/ 0.4 (4SD) ALP: L1/ 4.0/ 8.0/ 12.0 (3SD) ALP: L2/ 5/ 10/ 30 (6SD) ALT: L1/ 1.0/ 2.0/ 4.0 (4SD) ALT: L2/ 2/ 4/ 6 (3SD) AST: L1/ 1.0/ 2.0/ 4.0 (4SD) AST: L2/ 3/ 6/ 10 (3SD) TBili: L2/ 0.1/ 0.2/ 0.4 (4SD) CO2: L1/ 1.6/ 3.2/ 6.0 (4SD) CO2: L2/ 0.7/ 1.4/ 4.0 (5SD) Ca: L1/ 0.1/ 0.2/ 0.4 (4SD) Ca: L2/ 0.2/ 0.4/ 0.6 (3SD) Cl: L1/ 0.7/ 1.4/ 6.0 (8SD) Cl: L2/ 0.6/ 1.2/ 4.0 (6SD) Chol: L1/ 4/ 8/ 10 (2.5SD) Chol: L2/ 2/ 4/ 6 (3SD) Crea: L2: 0.1/ 0.2/ 0.4 (4SD) Dig: L2/ 0.1/ 0.2/ 0.4 (4SD) GGT: L1/ 1/ 2/ 6 (6SD) GGT: L2/ 1/ 2/ 6 (6SD) Glu: L1/ 1/ 2/ 6 (6SD) Mg: L2/ 0.1/ 0.2/ 0.4 (4SD) Phos: L1/ 0.1/ 0.2/ 0.4 (4SD) Phos: L2/ 0.1/ 0.2/ 0.4 (4SD) TP: L1/ 0.1/ 0.2/ 0.4 (4SD) Na: L1/ 1/ 2/ 4 (4SD) Na: L2/ 1/ 2/ 4 (4SD) UA: L1/ 0.1/ 0.2/ 0.4 (4SD) UA: L2/ 0.1/ 0.2/ 0.4 (4SD) D. Interview with technical consultant #2 (as listed on the CMS From 209) on April 1, 2025 at 1650 hours acknowledged she thought the 1SD field in the analyzer was a 2SD field. NOTE: Not all analytes' SDs were doubled. E. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed an annual test volume of 29,351 for the chemistries tested on the Roche Cobas Integra. KEY: BMP = Basic Metabolic Panel, comprised of: Sodium (Na), Potassium (K), Chloride (Cl), Carbon dioxide (CO2), Blood Urea Nitrogen (BUN), Creatinine (Crea), Glucose (Glu), Calcium (Ca) CMP = Comprehensive Metabolic Panel, comprised of: BMP, Aspartate Transaminase (AST), Alkaline Phosphatase (ALP), Total Bilirubin (T Bili), Total Protein (TP), Albumin (Alb), Alanine Transaminase (ALT) Renal Panel: Sodium (Na), Potassium (K), Chloride (Cl), Blood Urea Nitrogen (BUN), Creatinine (Crea), Calcium (Ca), Albumin (Alb) Chol = Cholesterol GGT = Gamma Glutamyl Transferase Mg= Magnesium UA = Uric Acid
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
Based on review of manufacturer instructions, the laboratory's policy and procedure, quality control (QC) records, LIS report, interview, and pre-survey paperwork, the laboratory failed to have control procedures that detected immediate errors for Aspartate Transaminase (AST), Carbon Dioxide (CO2), Calcium (Ca), Chloride (Cl), Digoxin (Dig) Gamma Glutamyl Transferase (GGT), Glucose (Glu), Magnesium (Mg), Total Protein (TP), Sodium (Na) when they used SDs as great as 4SD for the BioRad Lyphochek Assayed Chemistry Control tested on the Roche Cobas Integra chemistry analyzer for one of one months reviewed. Findings follow. A. Review of the BioRad Lyphochek Assayed Chemistry Control, 06/2023, under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product... It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." The values in the Assignment of Values Data Charts are +/- 3SD ranges requiring the laboratory to establish its own mean and ranges. B. Review of the laboratory's policy and procedure titled Internal Quality Control, revised 02/26/2025, stated, "Controls must be within the established 2 standard deviation acceptable range before patient testing can be performed. Before using new lot number of controls, 20 repetitive runs will be performed to calculate the mean and establish the 2SD range for each analyte." C. Review of the Roche Cobas Integra QC reports from 12/01/2024 - 12/31/2024 were reviewed against the laboratory established means and ranges shown on the Westgard QC Online QC Calculator records for each analyte. The following discrepancies were observed as listed by analyte, Level 1/2 (L1/L2), established 1SD, established 2SD, 2SD setting in analyzer (some equivalent to 4SD or greater) (see D5403). 1. AST: L1/ 1.0/ 2.0/ 4.0 (4SD) 2. AST: L2/ 3/ 6/ 10 (3SD) 3. CO2: L1/ 1.6/ 3.2/ 6.0 (4SD) 4. Ca: L1/ 0.1/ 0.2/ 0.4 (4SD) 5. Cl: L1/ 0.7/ 1.4/ 6.0 (8SD) 6. Cl: L2/ 0.6/ 1.2/ 4.0 (6SD) 7. Dig: L2/ 0.1/ 0.2/ 0.4 (4SD) 8. GGT: L2/ 1/ 2/ 6 (6SD) 9. Glu: L1/ 1/ 2/ 6 (6SD) 10. Mg: L2/ 0.1/ 0.2/ 0.4 (4SD) 11. TP: L1/ 0.1/ 0.2/ 0.4 (4SD) 12. Na: L2/ 1/ 2/ 4 (4SD) The laboratory ran two levels of controls on each day of patient testing. D. Review of the Roche Cobas Integra QC reports from 12/01/2024 - 12/31/2024 were reviewed against the laboratory established means and ranges shown on the Westgard QC Online QC Calculator records for each analyte against the values obtained on each run showed the following values would have been out of range had the laboratory used the 2SD ranges established by the laboratory as listed by analyte, L1/L2, the laboratory's established mean and range, and the runs reevaluated against the laboratory's established ranges: 1. AST: L1/ x = 39/ range = 37 - 41 outliers: a. 12/31/2024: 36 2. AST: L2/ x = 212/ range = 206 - 218 outliers: a. 12/12/2024: 219 3. CO2: L1/ x = 33/ range = 29.8 - 36.2 outliers: a. 12/19/2024: 28.9 b. 12/20/2024: 28.9 c. 12/21/2024: 28.4 d. 12/22/2024: 29.2 e. 12/23/2024: 28.2 f. 12/24/2024: 27.1 g. 12/25/2024: 27.3 h. 12/26/2024: 28.1 i. 12/27/2024: 27.6 j. 12/28/2024: 27.3 k. 12/29/2024: 25.5 l. 12/31/2024: 28.7 4. Ca: L1/ x = 9.1/ range = 8.9 - 9.3 outliers: a. 12/21/2024: 8.8 b. 12/24/2024: 8.7 c. 12/27/2024: 8.8 5. Cl: L1/ x = 105.6/ range = 104.2 - 107.0 outliers: a. 12/05/2024: 103.9 b. 12/09/2024: 103.7 c. 12/10/2024: 103.2 d. 12/11/2024: 103.8 e. 12/17/2024: 104.0 f. 12/20/2024: 103.7 g. 12/21/2024: 104.0 h. 12/22/2024: 103.6 i. 12/23/2024: 102.8 j. 12/25/2024: 104.0 k. 12/26/2024: 109.4 l. 12/27/2024: 109.2 m. 12/29/2024: 110.3 n. 12/30/2024: 110.3 o. 12/31/2024: 109.2 6. Cl: L2/ x = 86.8/ range = 85.6 - 88.0 outliers: a. 12/03/2024: 90.7 b. 12/04/2024: 90.5 c. 12/06/2024: 89.0 d. 12/07/2024: 88.5 e. 12/08/2024: 88.5 f. 12/09/2024: 88.8 g. 12/10/2024: 89.7 h. 12/11/2024: 89.3 i. 12/12/2024: 89.2 j. 12/13/2024: 89.4 k. 12/14/2024: 88.7 l. 12/15/2024:

89.2 m. 12/23/2024: 84.7 n. 12/26/2024: 89.3 o. 12/28/2024: 91.0 p. 12/29/2024: 88.5 q. 12/30/2024: 89.4 r. 12/31/2024: 89.0 7. Dig: L2/ x = 3.3/ range = 3.1 = 3.5 outliers: a. 12/29/2024: 3.0 8. GGT: L2/ x = 116/ range = 114 - 118 outliers: a. 12/03/2024: 112 b. 12/05/2024: 112 c. 12/09/2024: 112 d. 12/13/2024: 112 e. 12/17/2024: 110 f. 12/18/2024: 112 g. 12/29/2024: 111 h. 12/30/2024: 112 i. 12/31/2024: 111 9. Glu: L1/ x = 84/ range = 82 - 86 outliers: a. 12/02/2024: 88 b. 12/04/2024: 87 c. 12/08/2024: 87 d. 12/11/2024: 87 e. 12/14/2024: 89 f. 12/15/2024: 88 g. 12/16/2024: 88 h. 12/17/2024: 88 i. 12/18/2024: 88 j. 12/22/2024: 88 k. 12/24/2024: 88 l. 12/29/2024: 87 10. Mg: L2/ x = 4.4/ range = 4.2 - 4.6 outliers: a. 12/29/2024: 4.1 b. 12/30/2024: 4.1 c. 12/31/2024: 4.1 11. TP: L1/ x = 6.1/ range = 5.9 - 6.3 outliers: a. 12/22/2024: 6.4 b. 12/24/2024: 6.4 c. 12/26/2024: 6.4 d. 12/28/2024: 6.4 12. Na: L2/ x = 123/ range = 121 - 125 outliers: a. 12/23/2024: 120 b. 12/26/2024: 120 E. The following patients were tested on the above days of testing (at D) as listed below by specimen ID and test panel: 1. 12/02/2024: a. 24O-337C0001 CMP b. 24O-337C0003 CMP c. 24O-337C0004 CMP d. 24O-337C0005 BMP e. 24O-337C0006 CMP 2. 12/03/2024: a. 24O-338C0001 CMP b. 24O-338C0003 CMP c. 24O-338C0005 BMP d. 24O-338C0007 CMP e. 24O-338C0009 CMP f. 24O-338C0011 CMP g. 24O-338C0013 RFP h. 24O-338C0014 CMP i. 24O-338C0015 CMP j. 24O-338C0016 CMP 3. 12/04/2024: a. 24O-339C0001 BMP b. 24O-339C0003 CMP c. 24O-339C0004 BMP d. 24O-339C0007 CMP e. 24O-339C0008 CMP 4. 12/05/2024: a. 24O-340C0001 CMP b. 24O-340C0003 CMP c. 24O-340C0005 CMP d. 24O-340C0006 CMP e. 24O-340C0007 CMP 5. 12/06/2024: a. 24O-341C0001 CMP b. 24O-341C0002 CMP c. 24O-341C0003 CMP d. 24O-341C0004 CMP e. 24O-341C0005 CMP f. 24O-341C0006 BMP g. 24O-341C0008 CMP h. 24O-341C0010 BMP 6. 12/09/2024: a. 24O-344C0001 RFP b. 24O-344C0002 CMP c. 24O-344C0004 CMP d. 24O-344C0006 CMP e. 24O-344C0007 BMP f. 24O-344C0009 CMP g. 24O-344C0011 CMP h. 24O-344C0013 CMP i. 24O-344C0015 CMP 7. 12/10/2024: a. 24O-345C0002 CMP b. 24O-345C0004 BMP c. 24O-345C0006 BMP d. 24O-345C0007 CMP e. 24O-345C0008 RFP 8. 12/11/2024: a. 24O-346C0001 CMP b. 24O-346C0003 CMP c. 24O-346C0004 CMP d. 24O-346C0006 CMP e. 24O-346C0008 CMP f. 24O-346C0009 CMP g. 24O-346C0010 BMP h. 24O-346C0013 BMP 9. 12/12/2024: a. 24O-347C0001 BMP b. 24O-347C0003 CMP c. 24O-347C0004 CMP d. 24O-347C0006 CMP e. 24O-347C0007 BMP f. 24O-347C0009 CMP g. 24O-347C0012 CMP 10. 12/13/2024: a. 24O-348C0002 CMP b. 24O-348C0004 CMP c. 24O-348C0006 RFP d. 24O-348C0007 BMP e. 24O-348C0008 CMP f. 24O-348C0009 CMP g. 24O-348C0010 CMP 11. 12/16/2024: a. 24O-351C0001 BMP b. 24O-351C0002 CMP c. 24O-351C0003 CMP d. 24O-351C0005 CMP e. 24O-351C0007 BMP f. 24O-351C0009 BMP g. 24O-351C0010 CMP h. 24O-351C0012 CMP 12. 12/17/2024: a. 24O-352C0001 CMP b. 24O-352C0003 Glu c. 24O-352C0004 BMP d. 24O-352C0007 BMP e. 24O-352C0009 CMP f. 24O-352C0010 CMP g. 24O-352C0012 BMP h. 24O-352C0014 CMP i. 24O-352C0017 CMP 13. 12/19/2024: a. 24O-354C0002 CMP b. 24O-354C0004 BMP c. 24O-354C0005 CMP 14. 12/20/2024: a. 24O-355C0001 CMP b. 24O-355C0003 CMP c. 24O-355C0004 CMP d. 24O-355C0005 CMP e. 24O-355C0007 CMP f. 24O-355C0009 BMP g. 24O-355C0010 CMP h. 24O-355C0012 CMP i. 24O-355C0014 CMP j. 24O-355C0017 CMP 15. 12/22/2024: a. 24O-357C0001 CMP 16. 12/23/2024: a. 24O-358C0001 CMP b. 24O-358C0003 CMP c. 24O-358C0005 CMP d. 24O-358C0006 CMP e. 24O-358C0007 CMP f. 24O-358C0010 BMP 17. 12/26/2024: a. 24O-361C0001 CMP 18. 12/27/2024: a. 24O-362C0001 CMP b. 24O-362C0002 CMP c. 24O-362C0003 CMP d. 24O-362C0005 BMP e. 24O-362C0006 BMP 19. 12/30/2024: a. 24O-365C0001 CMP b. 24O-365C0003 RFP c. 24O-365C0004 CMP d. 24O-365C0005 CMP e. 24O-365C0006 BMP f. 24O-365C0007 CMP g. 24O-365C0009 BMP h. 24O-365C0011 CMP i. 24O-365C0013 CMP 20. 12/31/2024: a. 24O-366C0001 CMP b. 24O-

	366C0003 BMP c. 24O-366C0006 CMP d. 24O-366C0007 CMP e. 24O-366C0008 CMP F. Interview with technical consultant #1 (as listed on the CMS From 209) on April 1, 2025 at 1640 hours confirmed the findings. G. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed an annual test volume of 29,351 for the chemistries tested on the Roche Cobas Integra. KEY: BMP = Basic Metabolic Panel, comprised of: Sodium (Na), Potassium (K), Chloride (Cl), Carbon dioxide (CO2), Blood Urea Nitrogen (BUN), Creatinine (Crea), Glucose (Glu), Calcium (Ca) CMP = Comprehensive Metabolic Panel, comprised of: BMP, Aspartate Transaminase (AST), Alkaline Phosphatase (ALP), Total Bilirubin (T Bili), Total Protein (TP), Albumin (Alb), Alanine Transaminase (ALT) RFP = Renal Function Panel: Sodium (Na), Potassium (K), Chloride (Cl), Blood Urea Nitrogen (BUN), Creatinine (Crea), Calcium (Ca), Albumin (Alb) Chol = Cholesterol GGT = Gamma Glutamyl Transferase Mg= Magnesium UA = Uric Acid