Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2172772	01/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Brushy Creek Family Hospital	230 Deer Ridge Dr, Round Rock, 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 for an announced validation survey and found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, and interview, the laboratory failed to verify the accuracy of acetaminophen, ethanol, and salicylate at least twice annually for 1 of 1 years reviewed in 2023. Findings follow. A. Review of the American Proficiency Institute (API) PT records from 2023 showed one accuracy assessment for acetaminophen (Chemistry Core 3rd event 2023), and ethanol (remedial event in 2023), none for salicylate. Additional accuracy assessments were requested on January 10, 2024 at 1140 hours but not provided. B. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1140 hours acknowledged they weren't always able to participate in PT because they had no reagent or the instrument was down.
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 review of verification of performance specification records, interview, and patient test records, the laboratory failed to verify the performance specifications for Ethanol performed on the Siemens Vira-ProE for accuracy, precision, and reportable range for one of one years reviewed. Findings follow. A. Review of the validation for the Vira-ProE performed in 2022 showed no accuracy, precision, or reportable range for Ethanol. The verification of performance specifications was requested on January 10, 2024 at 1130 hours but not provided. B. Interview with the laboratory director /technical consultant #1 on January 10, 2024 at 1130 hours acknowledged the values from the verification of performance specifications was not entered to present the reports for accuracy, precision, and the reportable range, but would look for a set of reports. Follow-up interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1700 confirmed the reports could not be located. C. Review of test reports printed showed at least three patients were reported in 2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: I. Based on review of calibration verifications, interview, and test reports, the laboratory failed to perform calibration verifications every six months for Ethanol performed on the Siemens Vira-ProE for one of one years reviewed. Findings follow. A. Calibration verifications for Ethanol were requested on January 10, 2024 at 1145 hours but not provided. B. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1145 hours confirmed there were 2 calibrators used in the calibration of ethanol and calibration verifications on Ethanol were not performed. C. Review of test reports printed showed at least three patients were reported in 2023. II.

	Based on review of calibration verifications and interview, the laboratory failed to perform calibration verifications every six months for Thyroid Stimulating Hormone (TSH) performed on the Nano EnTek Frend for two of two years reviewed. Findings follow. A. Review of calibration verifications from 2022 and 2023 for TSH showed one performed 06/02/2023. Additional calibration verifications were requested on January 10, 2024 at 1545 hours but not provided. B. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1545 hours confirmed additional calibration verifications on TSH were not performed. III. Based on review of calibration verifications and interview, the laboratory failed to perform calibration verifications every six months for D-Dimer, Myoglobin, CKMB (Creatine Kinase-Myocardial Band), and Troponin I performed on the Triage for two of two years reviewed. Findings follow. A. Calibration verifications were requested on January 10, 2024 at 1635 hours but not provided. B. Interview with the laboratory director /technical consultant #1 on January 10, 2024 at 1635 hours confirmed calibration verifications were not performed.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of manufacturer instructions, quality control (QC) records, interview, and test reports, the laboratory failed have control procedures that detected immediate errors for acetaminophen and salicylate when they used 3SD ranges from the package insert as 2SD ranges with the BioRad Liquichek Therapeutic Drug Monitoring Controls (TDM) tested on the Siemens Vira-ProE for 10 of 10 months reviewed. Findings follow. A. Review of the Liquichek Therapeutic Drug Monitoring Control (TDM) package insert, 2022-04 5176-00, under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." The following 3SD ranges were listed in the data chart: 1. Acetaminophen in ug/mL Level 1 17.6 - 25.3 Level 2 41.2 - 59.5 Level 3 116 - 169 2. Salicylate in mg/dL Level 1 4.64 - 7.63 Level 2 16.0 - 25.0 Level 3 37.2 - 57.4 B. Review of the QC records from February and November 2023 showed the 3SD ranges from the package insert were used as 2SD: 1. Acetaminophen in ug/mL BR TDM CON 1 Low Limit 17.6 High Limit 25.3 BR TDM CON 2 Low Limit 41.2 High Limit 59.5 BR TDM CON 3 Low Limit 116 High Limit 169 2. Salicylate in mg /dL BR TDM CON 1 Low Limit 4.64 High Limit 7.63 BR TDM CON 2 Low Limit 16.0 High Limit 25.0 BR TDM CON 3 Low Limit 37.2 High Limit 57.4 C. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1050 hours confirmed he had no procedure for establishing the ranges, used the ranges from the package insert since installation and did not realize they represented 3SD. D. Review

	of test reports printed showed at least 15 Acetaminophen and 5 Salicylate tests were reported in 2023. II. Based on review of quality control (QC) records and interview, the laboratory failed to monitor over time the accuracy and precision of the test system for ethanol, acetaminophen, and salicylate performed on the Siemens Vira-ProE for 10 of 10 months reviewed. Findings follow. A. Review of QC results from February and November 2023 showed mean and standard deviation (SD) were not calculated for ethanol, acetaminophen, and salicylate. B. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1150 hours confirmed the laboratory did not monitor over time the accuracy and precision of the tests. III. Based on review of QC records and interview, the laboratory failed to monitor over time the accuracy and precision of the test system for Thyroid Stimulating Hormone (TSH) performed on the Nano EnTek Frend for 10 of 10 months reviewed. Findings follow. A. Review of QC records from February to November 2023 showed mean and standard deviation (SD) were not calculated for TSH. B. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1540 hours confirmed the laboratory did not monitor over time the accuracy and precision for TSH.
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 manufacturer instructions, quality control (QC) records, interview, and pre-survey paperwork, the laboratory failed to establish its own mean and SD (standard deviation) ranges for Thyroid Stimulating Hormone (TSH) using Cliniqa Liquid QC Immunoassay Control tested on the Nano EnTek Frend. Findings follow. A. Review of the Cliniqa Liquid QC Immunoassay Control package insert, 32928_07 8/24/18, under Assignment of Values stated, "The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation." The following Mean and Range of Means were listed in the data chart: 1. TSH uIU/mL for Nano EnTek Frend System, Lot 2008122A Level 1 1.10 0.63 - 1.57 Level 2 12.54 08.66 - 16.42 Level 3 25.16 18.94 - >25.00 B. Review of the QC records from February to November 2023 showed the following acceptable ranges for Lot 2008122A: LVL 1 Range 0.63 - 1.57 LVL 2 Range 8.66 - 16.42 C. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1530 hours confirmed he used the mean and ranges from the package insert. D. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed TSH was added in October 2019.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: .Based on review of competency evaluations, educational credentials, and interview, the technical consultant failed to perform the competency evaluations for 10 out of 24 randomly selected competency evaluations from 2022 and 2023. Findings follow. A. Review of competency evaluations showed the following competency evaluations were performed by testing personnel #13 (as listed on the CMS form 209): 1. annual competency evaluation performed on 06/11/2022 for testing personnel #7 2. 6 month competency evaluation performed on 03/27/2023 for testing personnel #10; 3. annual competency evaluation performed on 06/12/2022 for testing personnel #15; 4. annual competency evaluation performed on 04/04/2023 for testing personnel #15; 5. annual competency evaluation performed on 06/13/2022 for testing personnel #17; 6. annual competency evaluation performed on 05/10/2022 for testing personnel #20; 7. annual competency evaluation performed on 04/05/2023 for testing personnel #20; 8. annual competency evaluation performed on 05/07/2022 for testing personnel #28; 9. annual competency evaluation performed on 07/18/2023 for testing personnel #28; 10. annual competency evaluation performed on 08/28/2023 for testing personnel #30. B. Review of testing personnel #13 credentials revealed he had a high school diploma. C. Interview with the laboratory director/technical consultant #1 on January 9, 2024 at 1335 hours confirmed testing personnel #13 performed competency evaluations.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, competency evaluations, and interview, the technical consultant failed to evaluate and document the performance of individuals responsible for performing moderate complexity testing at least semiannually during the first year the individual tests patient specimens for two of two new employees reviewed. Findings follow. A. Review of the pre-survey paperwork titled Laboratory Personnel, and training and competency evaluation records showed: 1. testing personnel #10 (as listed on the CMS Form 209) was hired 08/24/2022. Training was performed 09/01/2022, and a six-month competency evaluation was performed 03/27 /2023. An additional competency evaluation was requested on January 9, 2024 at 1340 but not provided. 2. testing personnel #12 was hired 12/27/2021. Training was performed 11/23/2021, and a six-month competency evaluation was performed 05/10 /2022. The next competency evaluation was performed on 04/25/2023, one year later. B. Interview with the laboratory director/technical consultant #1 on January 10, 2024 at 1140 hours acknowledged he combined training with competency and had one set of documents for that.
D6063	LABORATORY TESTING PERSONNEL

	CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of pre-survey paperwork, educational credentials and interview, the laboratory failed to have documentation of education qualifying 5 of 15 testing personnel to perform non-waived testing. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, educational credentials and interview, the laboratory failed to ensure that 5 of 15 testing personnel reviewed for the moderately complex test systems had documentation of qualifying education prior to performing patient testing. Findings follow. A. Review of the pre-survey paperwork titled Laboratory Personnel showed: 1. testing personnel #10 (as listed on the CMS Form 209) was hired 08/24/2022; 2. testing personnel #17 was hired 07/17/2019; 3. testing personnel #22 was hired 08/23/2023; 4. testing personnel #28 was hired 09/20/2020; 5. testing personnel #30 was hired 06/04/2019. B. Review of the educational credentials showed: 1. testing personnel #10 had an Associate's Degree of Applied Science in Radiography, no transcript; 2. testing personnel #17 had a Bachelor of Arts, no transcript; 3. testing personnel #22 had a Bachelor of Science in Radiologic Science, no transcript showing transferred credits; 4. testing personnel #28 had a Bachelor of Science in Business Administration, no transcript; 5. testing personnel #30 had an Associate's Degree of Applied Science, no transcript. C. Interview with the laboratory director/technical consultant #1 on January 9, 2024 at 1600 hours confirmed the findings.