Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2086286	**(X3) Date Survey Completed** 12/06/2023
Name of Provider or Supplier Texas Health Outpatient Center Willow Park	**Street Address, City, State** 101 Crown Pointe Blvd, Willow Park, 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 found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, surveyor observations, and interview with laboratory personnel, the laboratory failed to centrifuge urine specimens for urine sediment analysis for the appropriate speed and time for one of two centrifuges used for preparing specimens for testing. The findings included: 1. Based on a review of the laboratory procedure "Urine Microscopic Exam", under 8.0 Procedure, the policy stated the following: "8.5 After completing the chemical analysis by urine dipstick, centrifuge the BD UA tube at 500 x g for 5 minutes. (Do not centrifuge if less than 1 mL of specimen)." 2. During a tour of the laboratory, the surveyor observed the Clay Adams Compact II Centrifuge that was identified as the primary centrifuge for processing urine samples for urine microscopic examinations had been checked by the laboratory's biomedical representatives to spin at 3,332 revolutions per minute (RPM) for 3 minutes. The Clay Adams centrifuge had a fixed speed/force: 3200rpm/1163 x g, which is greater than the 500 g the specimens were to be spun. 3. In an interview at 15: 01 hours on 12/05/2023, the laboratory manager confirmed specimens were spun for 3 minutes in the Clay Adams centrifuge prior to testing personnel performing urine microscopic analysis.
D5463	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(7)(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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and interview with laboratory personnel, the laboratory failed to rotate the performance of quality control among all operators who perform point of care testing for 24 of 24 testing personnel between January 2023 and October 2023. The findings included: 1. Based on a review of quality control records for the laboratory Abbott I-stat CG4+ and Chem 8 cartridges, Testing Person 9 (as listed on the CMS-209 Laboratory Personnel Report) performed quality control for 10 of the 10 months between January 2023 and October 2023. 2. Based on the CMS-209 laboratory personnel report, the laboratory listed 24 individuals who perform point of care testing with Abbott I-stats. None of the 24 point of care personnel performed the monthly quality control between January 2023 and November 2023. 3. In an interview at 2:28 pm on 11/05/23, Testing Person 9 confirmed she had performed all of the monthly Abbott I-stat point of care quality control for 2023.
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 laboratory policy, personnel files and confirmed in interview the technical consultant (TC) failed to evaluate and document the performance 2 of 33 Testing Persons (TP-14, TP-22 random review) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens in 2023. Findings included: 1. Review of the laboratory's personnel policy titled "Employee Orientation, Training, Competency, and Performance Evaluation Requirements for Laboratory" revealed: "4.0 Policy Guidance ... 4.4 New Employee Semi-Annual Technical Competency I Lab Specialty/s Technical must be evaluated: 4.4.1 Semi-annually for competency in all pertinent non-waved testing, 4.4.2 By designated Evaluators, and 4.4.3 During the first year of their employment." 2. Review of personnel records for TP-14 revealed an initial training assessment was performed on 08/17/2022 on the i-STAT chemistry analyzer. There was no documentation of a semiannual performance for the i-STAT chemistry analyzer. The laboratory was asked to provide the semiannual performance assessment, none were provided. Review of personnel records for TP-22 revealed an initial training assessment was performed on 02/08/2023 on the i-STAT chemistry analyzer. There was no documentation of a semiannual performance for the i-STAT chemistry analyzer. The laboratory was asked to provide the semiannual performance assessment, none were provided. 3. During an interview on 12/06/2023 at 9:22 am, the Laboratory Manager after review of records confirmed the above findings.