Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1010541	09/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Silsbee Family Medicine, Pa	280 Hwy 418 East, Silsbee, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory facility administration failed to ensure safety precautions were followed to ensure the safety of personnel as observed on September 17, 2025, at 13:40 hours. Refer to D3011.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation on September 17, 2025 at 13:40, review of laboratory policy, and confirmed in interview, the laboratory failed to ensure safety precautions were followed to ensure facility personnel did not store food or drinks in a biohazard indicated area. The findings included: 1. During an unannounced revisit conducted on September 17, 2025, the surveyor opened the laboratory refrigerator, located within in the laboratory with two large biohazard stickers and a handwritten note attached to the front that stated "No Food or Drink", to check for supplies, and observed the

	following: In the door of the refrigerator, located between proficiency testing samples from American Proficiency Institute (API) and a biohazard bag holding additional API specimens, included the following food items: Two Atkins Milk Chocolate Delight Protein Shakes One Can of Dr. Pepper Diet One open jar of Vlasic pickles In the body of the refrigerator, located in the vicinity and against, proficiency testing samples, and patient samples (including fecal occult cards, strep screens, and urine drug screens) included the following food items: Two to-go containers with food in them. Two Lunchables Two yogurt cups A cardboard 12 pack of Dr. Pepper Diet, open with cans missing. In an interview on 9/17/2025 at 13:40, in the laboratory, testing personnel (TP) 1 acknowledged the food in the specimen and reagent refrigerator. 2. Review of the laboratory policy titled "Universal Precautions for Infectious Blood & Body Fluid", section "Procedure" included the following instructions: "9. Due to the biohazardous conditions within the laboratory, the following should be considered: a. No food or drink will be allowed anywhere in the biohazard area." 3. In an interview on 9/17/2025 at 1530 hours, in the office, the practice manager confirmed food and drink were not supposed to be in the laboratory biohazard refrigerator.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on an unannounced survey performed on 9/17/2025 to assess compliance with deficiencies cited on 7/1/2025, surveyor observations, manufacturer's instructions, quality control (QC) results, patient reports, and interviews, the laboratory failed to meet the analytic requirements, specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299, for chemistry testing performed on the Clinitek 100 Urine Chemistry Analyzer, for patient testing from July 2025 through September 17, 2025. The findings included: 1. Based on surveyor observation, manufacturer's instructions for use (IFU), review of laboratory quality control records, patient test worksheets, and confirmed in interview, the laboratory failed to remove expired controls from use for 63 days past expiration when testing patient specimens. Refer to D5417. 2. Based on review of laboratory QC records, laboratory patient testing, and interview, the failed to have a mechanism in place to detect immediate errors for QC on the Clinitek 100 urine chemistry analyzer from July through September 17, 2025. Refer to D5441. 3. Based on review of laboratory policy, laboratory QC documentation, patient testing, and confirmed in interview, the failed to ensure the documentation of two levels of quality control each day of patient testing for the Siemens Multisix 10G Urine Dipstick, performed on the moderate complexity Clinitek 100 Urine Chemistry Analyzer for six of six patients. Refer to D5447.
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 surveyor observation, review of laboratory policy, laboratory demonstration, and confirmed in interview, the laboratory did not have a mechanism in place to detect immediate errors for the KOVA-Trol urine QC performed on the Clinitek 100 urine chemistry analyzer for QC performed from July 2025 to September 17, 2025. The findings included: 1. During an unannounced revisit on 9/17/2025, the surveyor noted reconstituted KOVA-Trol with a prep date of 7/7/2025 and expiration of 7/14 /2025. Surveyor asked if any additional KOVA-Trol was available for daily QC testing. Testing personnel (TP)1 confirmed the laboratory had lypholized reagent bottles available for reconstitution and use. Surveyor requested the controls be reconstituted according to the manufacturer's instructions in order to demonstrate the performance of quality control. 2. Review of the laboratory document titled "Control Log - Urine Dipstick & Microalbumin Urinalysis Test" included a space for the expected values of the following normal and abnormal quality control results: Glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilirubin, nitrate, leukocyte esterase, microalbumin. 3. In a demonstration on 9/17/2025 at 15:00 TP1 performed normal and abnormal quality control for the following tests on the Clinitek 100 urine analyzer: Siemens Multistix 10G Urine Dipstick: for the testing of urine Glucose, Bilirubin, Ketones, Specific Gravity, pH, protein, urobilinogen, nitrate, blood, leukocytes. Microalbumin 2 Reagent Strips: for the testing of urine microalbumin and urine creatinine Surveyor asked for the QC acceptability to ensure the QC was within expected range and none could be provided. 4. Review of laboratory QC documentation for July, August, through September 16, 2025, did not include the expected acceptability for the KOVA-Trol normal and abnormal controls for the following lots: Normal Control Lot K306732 Abnormal Control Lot K306750 5. Review of patient testing in July, August, and through September 16 included 307 patients (see patient crosswalk for complete list) to include the following sampling of 10: Date of test: Patient ID, Test Performed 07/02/2025: Patient K, Urinalysis, urine albumin, urine microalbumin 07/08/2025: Patient 1I, Urinalysis, urine albumin, urine microalbumin 07/14/2025: Patient 3K, Urinalysis, urine albumin, urine microalbumin 07/24/2025: Patient 6K, Urinalysis 08/14/2025: Patient 7W, Urinalysis, urine albumin, urine microalbumin 08/18/2025: Patient 8D, Urinalysis 08/26/2025: Patient 8Q, Urinalysis, urine albumin, urine microalbumin 08/28/2025: Patient 9R, Urinalysis, urine albumin, urine microalbumin 09/04/2025: Patient 10X, Urinalysis, urine albumin, urine microalbumin 09/05/2025: Patient 10Y, Urinalysis 6. In an interview on 9/17/2025 at 15:20, in the laboratory, TP1 confirmed the laboratory did not have QC acceptability for the KOVA-Trol abnormal and normal QC available for the evaluation of daily QC and to detect immediate errors in the test system.