Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1010541	**(X3) Date Survey Completed** 07/01/2025
Name of Provider or Supplier Silsbee Family Medicine, Pa	**Street Address, City, State** 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**
D0000	The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey on July 1, 2025. The following conditions were not met: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: I. Based upon review of the CMS 116 application, proficiency testing records and interview of facility personnel, the laboratory failed to enroll in a proficiency testing program for Urinalysis in 2025. The findings included: 1. Review of the CMS 116 application found the laboratory reported an estimated annual volume of 476 urinalysis tests. 2. Review of the American Proficiency Testing (API) proficiency testing records offered for 2023, 2024 and 2025 found no Urinalysis proficiency testing records for 2025. 3. During interview of the office manager conducted July 1, 2025 at 10:52 AM, she confirmed that she had not enrolled in a proficiency testing program for Urinalysis in 2025. 45469 II. Based on review of the laboratory testing menu, laboratory proficiency testing records, and confirmed in interview, the laboratory failed to ensure enrollment for urine creatinine testing on the moderate

	complexity Clinitek 100 Urine Chemistry Analyzer, for records reviewed in 2023, 2024, and January through July 2025. The findings included: 1. Review of the laboratory provided test menu included the following moderate complexity general chemistry performed on the Clinitek 100 Urine Chemistry Analyzer: Urine Creatinine 2. Review of laboratory proficiency testing for 2023, 2024, and January through June 2025 did not include proficiency testing for urine creatinine. Surveyor asked for documentation that proficiency testing was performed, and none was provided. 3. In an interview on 7/1/2025 at 10:53 hours, in the break room, the laboratory manager confirmed the laboratory was not enrolled in proficiency testing for urine creatinine in 2023, 2024 and from January through June 2025.
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 the laboratory testing menu, laboratory proficiency testing records, and confirmed in interview, the laboratory failed the twice annual accuracy for urine microalbumin testing on the moderate complexity Clinitek 100 Urine Chemistry Analyzer, for records reviewed in 2023 and 2024. The findings included: 1. Review of the laboratory provided test menu included the following moderate complexity general chemistry: Urine Microalbumin 2. Review of laboratory proficiency testing for 2023 and 2024 did not include proficiency testing for urine microalbumin. Surveyor asked for documentation of a twice annual accuracy assessment, and none was provided. 3. In an interview on 7/1/2025 at 10:53 hours, in the break room, the laboratory manager confirmed a twice annual accuracy assessment had not been performed for urine microalbumin in 2023 and 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon observations, review of policies and procedures, manufacturers instructions, quality control logs and interview of facility personnel, the laboratory used expired KOVA-Trol Urinalysis quality control materials levels I and III for 86 days past expiration when testing patient specimens. The findings included: 1. Observations made during the inspection found the laboratory was currently using the KOVA-Trol urinalysis controls level I (lot K306732 labeled as opened on 02/25/2025, with an expiration date of 03/25/2025) and III (lot K306750 labeled as opened on 02 /25/2025 with an expiration date of 03/2025). 2. Review of the laboratory's own written policy titled Urinalysis Routine found on page 2 under the heading CONTROLS: "KOVA-Trol III (Normal) Reconstitution: Add 60 or 15 ml of distilled water to the vial of control. Allow to sit at room temperature for 30 minutes. Swirl and invert to mix. The control is ready to use. Refrigerate after using control. Control is found to be stable for five days when kept at 2-8 C. KOVA-Trol I (Abormal)

	Reconstitution: Add 60 or 15 ml of distilled water to the vial of control. Allow to sit at room temperature for 30 minutes. Swirl and invert to mix. The control is ready to use. Refrigerate after using control. Control is found to be stable for five days when kept at 2-8 C." 3. Review of the manufacturer's instructions for use found under the heading Stability and Storage: "The lypholyzed KOVA-Trol product is stable until the expiration date stated on the label when stored between 2 - 8C. Following reconstitution, keep the liquid KOVA-Trol stoppered and refrigerated. When KOVA-Trol is properly reconstituted and stored at 2- 8C, the constituents are stable from the date of reconstitution for a maximum of seven (7) days." 4. Review of quality control logs found the laboratory used expired control materials for 86 days after expiration of the control material reconstituted on February 25, 2025. 5. During interview of testing person one on the CMS Report 209 conducted July 1, 2025 at 12:11 PM, she confirmed that she was currently using the reconstituted controls to ensure the accuracy of urinalysis results each day of patient testing, recording the results on the urinalysis control log. She went on to say she reconstitutes new controls once every 30 days and stores them in the refrigerator for daily use.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of laboratory test list, laboratory policy, laboratory quality control documents, patient reports, and confirmed in interview, the laboratory failed to document two levels of quality control, each day of patient testing, for urine microalbumin and creatinine testing performed on the Clinitek 100 Urine Chemistry Analyzer for nine of nine patients tested for records reviewed from April 2025 through June 2025. The findings included: 1. Review of the laboratory test list included urine microalbumin and urine creatinine, using the Clinitek Microalbumin2 /Creatinine strips, performed on the Clinitek 100 Urine Chemistry Analyzer. 2. Review of the laboratory policy titled "Quality Control Procedures" included the following instructions: "5. Two levels (usually one Normal and one Abnormal) controls are required for each test/instrument at the beginning of each day (or time performed if not performed daily) ..." 3. Review of the laboratory urinalysis control log sheet did not include a spot for the documentation of acceptable urine creatinine testing results. Under the column labeled MALB (microalbumin) no quantitative number was recorded, only a 'check' mark. Surveyor asked if the Clinitek 100 provided quantitative results for the urine microalbumin and urine creatinine testing and for the QC documentation. Testing personnel (TP) 1 stated the results were quantitative, but the laboratory did not record them. 4. Review of patient worksheets from April 2025 to June 16, 2025, included the following nine patients (refer to patient crosswalk for identifiers) with urine microalbumin and urine creatinine testing performed on days where quality control was not documented. Date Of Testing Patient ID 04/02/2025 Patient B 05/06/2025 Patient D 05/07/2025 Patient E 05/12 /2025 Patient F 05/13/2025 Patient G 05/15/2025 Patient H 06/04/2025 Patient I 06/12 /2025 Patient J 06/16/2025 Patient K 5. In an interview on 7/1/2025 at 11:35 hours, in the laboratory, TP 1 confirmed urine microalbumin and urine creatinine had not been documented for the above days before patient testing occurred.
D5807	TEST REPORT

	CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory testing, laboratory policy, patient test results, and confirmed in interview, the laboratory failed to ensure pertinent reference intervals were included on the patient final report for two of two tests being performed on moderate complexity Clinitek 100 Urine Chemistry Analyzer, for 14 of 14 patients reviewed. The findings included: 1. Review of the laboratory provided test list included urine testing on the Clinitek 100 urine analyzer for the following: 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 2. Review of the laboratory policy titled "Normal Reference Ranges, Laboratory Test Results" included the following normal reference ranges established for patient testing: "Urinalysis: Parameter Normal Color Straw to yellow Appearance Clear to slightly hazy Leukocytes Negative Nitrite Negative Urobilinogen Negative Protein Negative pH 4.6 - 8.0 Blood Negative Sp. Gravity 1.003 - 1.030 Ketone Negative Bilirubin Negative Glucose Negative" Surveyor asked for the reference range for the Urine Microalbumin and Urine Creatinine tests, and none could be provided. 3. Review of the following 14 patient final test reports (refer to patient crosswalk for identifiers) did not include normal patient reference ranges: Date Of Testing, Patient ID: Test 12/03 /2024, Patient A: Urinalysis 04/02/2025, Patient B: Urinalysis, urine microalbumin, urine creatinine 04/09/2025, Patient C: Urinalysis 05/06/2025, Patient D: Urinalysis, urine microalbumin, urine creatinine 05/07/2025, Patient E: Urinalysis, urine microalbumin, urine creatinine 05/12/2025, Patient F: Urinalysis, urine microalbumin, urine creatinine 05/13/2025, Patient G: Urinalysis, urine microalbumin, urine creatinine 05/15/2025, Patient H: Urinalysis, urine microalbumin, urine creatinine 06 /04/2025, Patient I: Urinalysis, urine microalbumin, urine creatinine 06/12/2025, Patient J: Urinalysis, urine microalbumin, urine creatinine 06/16/2025, Patient K: Urinalysis, urine microalbumin, urine creatinine 06/30/2025, Patient L: Urinalysis 07 /01/2025, Patient M: Urinalysis 07/01/2025, Patient N: Urinalysis 4. In an interview on 7/1/2025 at 11:11 hours, in the laboratory, testing personnel (TP) 1 confirmed normal patient ranges for urinalysis, urine microalbumin, and urine creatinine, were not available on the patient final reports.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of direct observation, laboratory policy, laboratory proficiency testing, laboratory quality control, and laboratory quality assurance documents, the laboratory director failed to ensure testing personnel followed the procedure for use of the KOVA-Trol urinalysis quality controls in 2023, 2024 and 2025 (See D 6014), the

	laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for non-waived urinalysis testing in 2025 (See D 6015), the laboratory director failed to ensure the QC and QA programs intended to identified failures as they occurred for records reviewed from 2023 through June 2025 (see D6020).
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: The laboratory director failed to ensure testing personnel followed the procedure for use of the KOVA-Trol urinalysis quality controls in 2023, 2024 and 2025. (See D 5417)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: The laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for non-waived urinalysis testing in 2025. (See D2000 I and II)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment policy, laboratory patient results, laboratory quality control records, laboratory proficiency testing, and confirmed in interview, the laboratory director failed to ensure the QC and QA programs intended for the monthly review of laboratory compliance, identified failures as they occurred for records reviewed from 2023 through June 2025. The findings included: 1. Review of the laboratory policy titled "Quality Assurance Program Guildlines" included the following areas of review: "Analytical Guidelines" Annual Review Goal: 90% compliance 1) Test Requisition/Report a) Does the test requisition/report contain the following: ... Reference range? ... 2) Quality control Monthly Monitoring Goal: 100% compliance a) Are at least two levels of control run each day of testing for every test? ... g) Are two levels of quality control within acceptable ranges prior to testing and reporting patient values? 3) Proficiency Testing Three Cycle Per Year, Goal: 100% Compliance, Goal 80% of sample results a) is the lab enrolled in an approved proficiency testing program for each specialty and subspecialty for which it seeks certification? ..." 2. Based review of laboratory patient results the laboratory failed to ensure pertinent reference intervals were included on the patient final report for two of

	two tests being performed on moderate complexity Clinitek 100 Urine Chemistry Analyzer, for 14 of 14 patients reviewed. Refer to D5807. 3. Based on review of the laboratory quality control documents the laboratory failed to document two levels of quality control, each day of patient testing, for urine microalbumin and creatinine testing performed on the Clinitek 100 Urine Chemistry Analyzer for nine of nine patients tested for records reviewed from April 2025 through June 2025. D5447. 4. Based on review of the laboratory proficiency testing records the laboratory failed to ensure enrollment for urine creatinine testing on the moderate complexity Clinitek 100 Urine Chemistry Analyzer, for records reviewed in 2023, 2024, and January through July 2025. (D2000 II) 5. In an interview on 7/1/2025 at 12:30 hours, in the break room, the office manager confirmed the quality assurance program and checklists had not been successful in identifying the above failures as they occurred.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) (b) Each individual performing moderate complexity testing must-- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; This STANDARD is not met as evidenced by: Based upon observations, review of policies and procedures, manufacturers instructions and interview of facility personnel, testing personnel failed to follow the laboratory's own written policy for the use of urinalysis controls beyond the reconstituted expiration date. (See D5417)