Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471917	04/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Schafer Medical Center	800 Isabel Sw, Ardmore, OK	

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 recertification survey was performed on 04/08/2026. The laboratory was found out of compliance with the following CLIA Conditions: 493.1213; D5022: Toxicology, High Complexity 493.1441; D6076: Laboratory Director, High Complexity
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with testing person #1, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology for 20 of 20 months of patient testing. Findings include: (1) The laboratory failed to have written policy defining the method to verify the accuracy of the urine drug screen testing at least twice annually. Refer to D5217; (2) The laboratory failed to establish the performance specifications for the McKesson Drugs of abuse test cups 12-drug panel with adulterants test not cleared or approved by the FDA. Refer to D5423; (3) The laboratory failed to perform a negative and positive control material 32 of 32 days of patient urine drug screen testing. Refer to D5449.
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: ased on a review of records, policies and procedures and interview with testing person #1, the laboratory failed to verify the accuracy of the urine drug screen testing at least twice annually during a review period of 07/01/2024 through 04/08/2026. Findings include: (1) On 04/08/2026 at 10:30 am, testing person #1 stated the McKesson Drugs of Abuse Test Cups 12-Drug Panel with Adulterants test devices had been put into use for patient testing on 07/22/2024 (refer to D5423 for specific information pertaining to the test kit not being FDA approved and defaulting to a high complexity test system); (2) A review of urine drug screen records, policies and procedures, and proficiency testing for 2024,2025, and 2026 revealed the laboratory had not enrolled and participated in a proficiency testing program and there was no evidence a policy had been written to ensure a method to verify the accuracy of the testing at least twice annually; (3) The records were reviewed with testing person #1 who stated on 04/08 /2026 at 10:30 am the laboratory did not have a method to verify the accuracy of urine drug screen testing at least twice annually because it was believed the test kit was categorized as waived; (4) Refer to D5423 for examples of patient testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with FDA representative, and interview with testing person #1, the laboratory failed to establish the performance specifications for the McKesson Drugs of Abuse Test Cups 12-Drug Panel with Adulterants Test Device not categorized by the FDA. Findings include: (1) On 04/08/2026 at 10:30 am, testing person #1 stated urine drug screen testing was performed using the McKesson Drugs of Abuse Test Cups 12-Drug Panel with Adulterants test kit, as stated on the test kit box; (2) On 04/08/2026 a review of the urine drug screen package insert showed the name of the test kit "Multi-Drug Panel with Adulterants" which did not match the name on the test kit box, "Drugs of abuse test cups"; (3) A review of the FDA (Food and Drug Administration) test classification database did not include a classification for the test kit (if a test is not included on the FDA site, then it did not go through the FDA approval process, which defaults the categorization of the test as high complexity). This was also confirmed during email correspondence with an FDA representative on 04/10/2026; (4) Interview with testing person #1 on 04/08/2026 at 10:30 am confirmed the test kit had been put into use for patient testing on or around 07/1/2024; (5) A review of records for the test system revealed no evidence the performance specifications of accuracy, precision, analytical sensitivity, analytical

	specificity, reportable range, and reference intervals as applicable, had been established prior to putting the test into use for patient testing; (6) The findings were reviewed with the technical consultant, who stated on 04/08/2026 at 10:30 am the laboratory did not establish the performance specifications prior to putting the test kit into use because it was believed the test kit was categorized as waived; (7) The following were examples of patient urine drug screen testing performed (number represents accession number): (a) Patient #10013140 - Testing performed on 07/22 /2024 (b) Patient #H000003202B - Testing performed on 08/15/2024 (c) Patient #H00075596 - Testing performed on 09/05/2024 (d) Patient #H00055770 - Testing performed on 10/14/2024 (e) Patient #10012750 - Testing performed on 11/07/2024 (f) Patient #H00055724 - Testing performed on 01/01/2025 (g) Patient #H00025338B - Testing performed on 01/15/2025 (h) Patient #H00074427 - Testing performed on 02 /19/2025 (i) Patient #H00076050 - Testing performed on 03/10/2025 (j) Patient #H00068237B - Testing performed on 03/26/2025 (k) Patient #C00075685 - Testing performed on 04/14/2025 (l) Patient #H00053095A - Testing performed on 04/25 /2025 (m) Patient #100086440 - Testing performed on 05/13/2025 (n) Patient #H00009311 - Testing performed on 05/14/2025 (o) Patient #C00073727B - Testing performed on 06/03/2025 (p) Patient #H00002275A - Testing performed on 06/12 /2025 (q) Patient #10012630 - Testing performed on 06/19/2025 (r) Patient #H00014161A - Testing performed on 07/02/2025 (s) Patient #10012660 - Testing performed on 07/03/2025 (t) Patient #H000001351A - Testing performed on 07/15 /2025 (u) Patient #C00075887 - Testing performed on 08/07/2025 (v) Patient #H00045102 - Testing performed on 08/20/2025 (w) Patient #H00041427 - Testing performed on 09/03/2025 (x) Patient #H00075687 - Testing performed on 09/22/2025 (y) Patient #H00001243B - Testing performed on 10/07/2025 (z) Patient #H00011151 - Testing performed on 11/19/2025 (aa) Patient #10009480 - Testing performed on 12 /01/2025 (bb) Patient #10011980 - Testing performed on 01/14/2026 (cc) Patient #H00010133 - Testing performed on 01/19/2026 (dd) Patient #H00016200 - Testing performed on 02/03/2026 (ee) Patient #H00075693 - Testing performed on 02/11 /2026 (ff) Patient #10010880 - Testing performed on 02/23/2026
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to perform a negative and positive control material 29 of 29 days of patient urine drug screen testing. Findings include: (1) On 04/08/2026 at 10:35 am, testing person #1 stated the McKesson Drugs of abuse test cups had been put into use for patient testing on or around 07/01/2024 (refer to D5423 for specific information pertaining to the test kit not being FDA approved and defaulting to a high complexity test system); (2) A review of QC (Quality Control) and patient testing records from July 2024 through March of 2026, revealed negative and positive QC materials had not been performed each day of patient testing for 29 of 29 days of patient testing and there was no evidence an IQCP (Individualized Quality Control Program) had been developed; (3) The technical consultant stated on 04/08/2026 at 10:35 am negative and positive QC materials had not been performed each day of patient testing and an IQCP had not been developed because it was believed the test kit was categorized as waived; (4) The following were the days of patient testing reviewed when negative and positive QC materials had not been performed: (a) Patient #10013140 - Testing

	performed on 07/22/2024 (b) Patient #H000003202B - Testing performed on 08/15 /2024 (c) Patient #H00075596 - Testing performed on 09/05/2024 (d) Patient #H00055770 - Testing performed on 10/14/2024 (e) Patient #10012750 - Testing performed on 11/07/2024 (f) Patient #H00055724 - Testing performed on 01/01/2025 (g) Patient #H00025338B - Testing performed on 01/15/2025 (h) Patient #H00074427 - Testing performed on 02/19/2025 (i) Patient #H00076050 - Testing performed on 03 /10/2025 (j) Patient #H00068237B - Testing performed on 03/26/2025 (k) Patient #C00075685 - Testing performed on 04/14/2025 (l) Patient #H00053095A - Testing performed on 04/25/2025 (m) Patient #100086440 - Testing performed on 05/13/2025 (n) Patient #H00009311 - Testing performed on 05/14/2025 (o) Patient #C00073727B - Testing performed on 06/03/2025 (p) Patient #H00002275A - Testing performed on 06/12/2025 (q) Patient #10012630 - Testing performed on 06/19/2025 (r) Patient #H00014161A - Testing performed on 07/02/2025 (s) Patient #10012660 - Testing performed on 07/03/2025 (t) Patient #H000001351A - Testing performed on 07/15 /2025 (u) Patient #C00075887 - Testing performed on 08/07/2025 (v) Patient #H00045102 - Testing performed on 08/20/2025 (w) Patient #H00041427 - Testing performed on 09/03/2025 (x) Patient #H00075687 - Testing performed on 09/22/2025 (y) Patient #H00001243B - Testing performed on 10/07/2025 (z) Patient #H00011151 - Testing performed on 11/19/2025 (aa) Patient #10009480 - Testing performed on 12 /01/2025 (bb) Patient #10011980 - Testing performed on 01/14/2026 (cc) Patient #H00010133 - Testing performed on 01/19/2026
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with testing person #1, the laboratory director failed to provide overall management and direction for a urine drug screen test for twenty of twenty months of testing. Findings include: (1) The laboratory director failed to ensure the McKesson Drugs of abuse test cups 12-drug panel with adulterants drug screen test provided quality results for patient care for twenty of twenty months of testing. Refer to D6085.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with FDA representative, and interview with testing person #1, the laboratory director failed to ensure a urine drug screen test provided quality results for patient care for 20 of 20 months of patient testing. Findings include:

	(1) The laboratory director failed to ensure the FDA categorization of the McKesson Drugs of Abuse test cups 12-drug panel with adulterants device prior to using for patient testing. Refer to D5217, D5423, and D5449.