Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2065292	02/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vipcare Bristow	300 N Main, Bristow, 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 02/23/2023. The laboratory was found out of compliance with the following CLIA Conditions: 493.1240; D5300: Preanalytic Systems 493.1403; D6000: Laboratory Director The findings were reviewed with the laboratory director and testing person at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory director failed to sign proficiency testing attestation statements for eight of eight events reviewed in 2021 and 2022. Findings include: (1) On 02/23/2023 at 09:30 am, the laboratory director stated the laboratory performed Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, Oxycodone, pH, and Specific Gravity using urine specimens and the Thermofisher Indiko Plus analyzer; (2) A review of 2021 and 2022 proficiency testing records identified the following for eight of eight events: (a) Second 2021 UDS-B Event (Urine Drug Screen) - The attestation statement had not been signed by the laboratory director; (b) Second 2021 DAI-B Event (Urine Drug Adulterant) - The attestation

	statement had not been signed by the laboratory director; (c) Third 2021 UDS-C Event - The attestation statement had not been signed by the laboratory director; (d) First 2022 UDS-A Event - The attestation statement had not been signed by the laboratory director; (e) First 2022 DAI-A Event - The attestation statement had not been signed by the laboratory director; (f) Second 2022 UDS-B Event - The attestation statement had not been signed by the laboratory director; (g) Second 2022 DAI-B Event - The attestation statement had not been signed by the laboratory director; (h) Third 2022 UDS-C Event - The attestation statement had not been signed by the laboratory director. (3) The findings were reviewed with the laboratory director who stated on 02/23/2023 at 10:50 am the attestation statements had not been signed by the laboratory director.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to review and evaluate proficiency testing results for one of three Urine Drug Adulterant events reviewed. Findings include: (1) A review of Urine Drug Adulterant proficiency testing records for the third 2021, first 2022, and second 2022 events identified the following failure for one of three events: (a) DAI-B 2022 Event (i) Creatinine - The laboratory failed the results for one of three samples (DAI-04). There was no documentation to prove that remedial action had been taken for the failure. (2) The records were reviewed with the laboratory director who stated on 02/23/2023 at 10:40 am, there was no evidence that remedial action had been taken for the failure.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory director and testing person, the laboratory failed to monitor and evaluate the overall quality of preanalytic systems. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for storing patient urine specimens prior to urine drug screen testing. Refer to D5311,
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory director and testing person, the laboratory failed to follow the manufacturer's instructions for storing patient urine specimens prior to urine drug screen testing for 50 of 50 patient specimens. Findings include: (1) On 02/23/2023 at 09:30 am, the laboratory director stated the laboratory performed qualitative Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone testing using urine specimens and the Thermofisher Indiko Plus analyzer; (2) Observation of the laboratory refrigerator on 02/23/2023 at 11:51 am identified 50 patient urine samples in specimen collection cups being stored at 2-8 degrees C (Centigrade); (3) The laboratory director and testing person explained during an interview on 02/23/2023 at 11:55 am, the reagents used to perform urine drug testing were on back order with the manufacturer and the laboratory was storing the urine specimens in the refrigerator until the reagents were received and the testing could be performed. It could not be determined when the reagents would be shipped; (4) A review of the manufacturer's package inserts for the above analytes identified the following storage requirements under "Specimen Collection and Handling": (a) Barbiturate - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to 7 days. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C"; (b) Benzodiazepine - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to two months. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C"; (c) Buprenorphine - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to 30 days. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C"; (d) Cocaine - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to two months. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C"; (e) Methadone - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to thirty days. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C"; (f) Opiate - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to two months. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C"; (h) Oxycodone - "Specimens kept at room temperature that do not receive initial testing within 7 days of arrival at the laboratory may be placed into a refrigeration unit at 2 to 8 C for up to two months. For longer storage prior to analysis or sample retention after analysis, urine samples may be stored at -20 C". (5) A review of the patient specimen logs for the patient specimens that were being stored in the refrigerator identified: (a) The following patient specimens were beyond the stability for testing the analytes Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone: (i) Patient #26703 and #22979 - collected on 12/19/2022 (ii) Patient

	#22876, #23509, and #27708 - collected on 12/20/2022 (ii) Patient #24742 - collected on 12/21/2022 (b) The following patient specimens were beyond the stability for testing the analytes Barbiturate, Buprenorphine, and Methadone: (i) Patient #23725, #25270, #23292, and #26600 - collected on 12/27/2022 (ii) Patient #27113 and #29526 - collected on 12/28/2022 (iii) Patient #26620, #26294, #26185, and #22835 - collected on 12/29/2022 (iv) Patient #22768 - collected on 01/03/2023 (v) Patient #29498, #25060, and #21272 - collected on 01/04/2023 (vi) Patient #29204 - collected on 01/05/2023 (vii) Patient #24765, #23048, #28062, and #28370 - collected on 01/09 /2023 (viii) Patient #26948 and #28565 - collected on 01/10/2023 (ix) Patient #24024 and #28189- collected on 01/11/2023 (x) Patient #28917 and #25985 - collected on 01 /12/2023 (xi) Patient #26703, #25368, #27237, and #22979 - collected on 01/16/2023 (xii) Patient #22876 and #23509 - collected on 01/17/2023 (xiii) Patient #24742, #26826, and #29417 - collected on 01/18/2023 (c) The following patient specimens were beyond the stability for testing the analyte Barbiturate: (i) Patient #23725 and #24798 - collected on 01/24/2023 (ii) Patient #27113 - collected on 01/25/2023 (iii) Patient #22835 - collected on 01/26/2023 (iv) Patient #21272 - collected on 02/01 /2023 (v) Patient #28370, #24765, #24290, #23048, and #28062 collected on 02/06 /2023 (vi) Patient #26948, #28358, and #28565 - collected on 02/07/2023 (vii) Patient #28189 - collected on 02/08/2023 (viii) Patient #28917 and #28329 - collected on 02 /09/2023 (6) The findings were reviewed with the laboratory director and testing person. Both stated on 02/23/2023 at 12:00 pm, the above urine specimens were beyond the manufacturer's refrigerated storage stability.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to ensure the manufacturer's instructions were followed for performing daily maintenance procedures for three of three months reviewed during 2022. Findings include: (1) On 02/23/2023 at 09:30 am, the laboratory director stated the laboratory performed Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, Oxycodone, pH, and Specific Gravity using urine specimens and the Thermofisher Indiko Plus analyzer; (2) A review of the manufacturer's maintenance log showed the following required daily maintenance procedures: (a) "Beginning of Day" (i) "Wipe up condensed water from reagent storage (if necessary)" (ii) "Check and/or fill DI water container" (iii) "Load Tencell cuvettes (if necessary)" (iv) "Perform start up (check water blank if necessary)" (v) "Check reagent volumes" (b) "End of Day" (i) "Run Stand by procedure" (ii) "Remove samples" (iii) "Clear daily files" (iv) "Wipe up condensed water from reagent storage (if necessary)" (v) "Clean reagent/sample racks (if necessary)" (vi) "Empty & clean solid waste & waste water containers" (3) A review of maintenance logs and patient testing records during January 2022, May 2022, and November 2022 identified the daily maintenance procedures had not been documented as performed six of 19 days of patient testing as follows: (a) January 2022 - not documented as performed two of six days of patient testing (01/07,31 /2022); (b) May 2022 - not documented as performed three of nine days of patient testing (05/09,26,27/2022); (c) November 2022 - not documented as performed one of

	four days of patient testing (11/03/2022). (4) The records were reviewed with the laboratory director and testing person. Both stated on 02/23/2023 at 12:23 pm, the daily maintenance had not been documented as performed as shown above.
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 a review of records, manufacturer's instructions, observation, and interview with the laboratory director and testing person, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure quality laboratory services for all aspects of test performance, which included the preanalytic phase of testing were provided. Refer to D6007; (2) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of 27 events. Refer to D6016.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory director and testing person, the laboratory failed to provide quality laboratory services for all aspects of test performance, which included the preanalytic phase of testing. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for storing patient urine specimens prior to urine drug screen testing. Refer to D5311.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of 27 events. Findings include: (1) The laboratory director failed to sign proficiency testing attestation statements for eight of eight events reviewed in 2021 and 2022. Refer to D2015.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to ensure competency evaluations had been performed at least annually for one of one testing person. Findings include: (1) On 02/23/2023 at 09:30 am, the laboratory director stated the laboratory performed urine drug screen testing for the analytes Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, Oxycodone, pH, and Specific Gravity using the Thermofisher Indiko Plus analyzer; (2) A review of personnel records for one person performing testing during 2020, 2021, 2022, and to date in 2023 identified an annual competency evaluation had not been documented as performed between 08/31/2020 and 01/03/2022; (3) The records were reviewed with the laboratory director who stated on 02/23/2023 at 10:00 am, an annual competency evaluation had not been performed as stated above.