

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2065292	(X3) Date Survey Completed 02/04/2021
Name of Provider or Supplier Vipcare Bristow	Street Address, City, State 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 initial survey was performed on 02/04/2021. The findings were reviewed with the laboratory director and the testing person during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to verify the accuracy of urine Creatinine, pH, and Specific Gravity testing at least twice annually. Findings include: (1) On 02/04/2021, the testing person stated to the surveyor at 10:00 am the laboratory performed Creatinine, pH, and Specific Gravity testing for urine drug specimens on the Thermofisher Indiko Plus analyzer; (2) The surveyor reviewed 2020 testing records. There was no documentation the testing had been verified for accuracy in 2020 through the day of the survey (02/04/2021); (3) The surveyor asked the testing person if urine Creatinine, pH, and Specific Gravity testing had been verified for accuracy in 2020 and through the date of the survey 02/04/2021. The testing person stated in an interview on 02/04/2021 at 05:00 pm the testing had not been verified for accuracy during the review period.</p>
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p>

This STANDARD is not met as evidenced by:

Based on an interview with the testing person, the laboratory failed to provide written instructions to clients collecting and referring urine drug specimens. Findings include: (1) On 02/04/2021, the testing person stated the following to the surveyor at 10:00 am: (a) The laboratory performed Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, Oxycodone, pH, and Specific Gravity testing for urine specimens on the Thermofisher Indiko Plus analyzer; (b) The urine specimens were transported to the laboratory from one outside clinic. (2) The surveyor asked the testing person if instructions (e.g., client service manual) had been written and provided to the client which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The testing person stated specimen handling instructions had not been written and provided to the client.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the testing person, the laboratory failed to have a policy to verify the stated value of control materials before they were put into use. Findings include: (1) On 02/04/2021, the testing person stated at 10:00 am the following to the surveyor: (a) The laboratory used the Thermofisher Indiko Plus analyzer to perform Toxicology (Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, Oxycodone, Creatinine, Specific Gravity, and pH) testing; (b) Quality control materials were analyzed each day of patient testing: (i) Two levels of MAS DOA Total control materials for Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Opiate, and Oxycodone testing; (ii) Three levels of Creatinine Detect control materials for Creatinine testing; (iii) Four levels of pH Detect control materials for pH testing; (iv) Two levels of Gravity Detect control materials for specific gravity testing. (c) The manufacturer's provided the instructions to determine acceptability of quality control

results as follows: (i) MAS DOA Total control materials - "All quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements."; (ii) Creatinine Detect control materials - "Ensure that control results are within the established range."; (iii) pH Detect control materials - "Ensure that control results are within the established ranges as determined by your laboratory."; (iv) Gravity Detect control materials - "Ensure that control results are within the established ranges as determined by your laboratory.". (2) The surveyor reviewed the laboratory's written Indiko Plus Procedure manual. A procedure to verify the stated value of control materials could not be located. (3) The surveyor asked the testing person if a written procedure to verify the manufacturer's stated value of control materials existed. The testing person stated on 02/04/2021 at 04:40 pm a procedure had not been written.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the testing person, the laboratory failed to ensure materials had been stored as required for 4 of 12 months. Findings include: (1) On 02/04/2021, the testing person stated to the surveyor at 10:00 am the laboratory performed Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, Oxycodone, pH, and Specific Gravity testing for urine specimens on the Thermofisher Indiko Plus analyzer. (2) On 02/04/2021 at 04:03 pm, the surveyor observed the following stored in the GE laboratory refrigerator, along with manufacturer's storage requirements of 2 to 8 degrees Centigrade (C): (a) 1 box of DRI Amphetamines Assay for the qualitative determination of amphetamines in human urine (lot#73886809); (b) 1 box of CEDIA Buprenorphine Assay for the qualitative determination of buprenorphine in human urine (lot#73684679); (c) 1 box of DRI Methadone Assay for the qualitative determination of methadone in human urine (lot#73794445); (d) 1 box of DRI Oxycodone Assay for the qualitative determination of oxycodone and its metabolite oxymorphone in human urine (lot#73766620); (e) 1 box of DRI pH-Detect Test for the determination of urine pH (lot #73875501). (3) The surveyor reviewed temperature records from January 2020 through December 2020. The documented refrigerator temperatures were colder than 2 C (the coldest temperature allowed for the materials) during 4 of 12 months as follows: (a) April - 1 of 22 temperatures had been documented as 1.5 degrees C; (b) August - 1 of 22 temperatures had been documented as 1.2 degrees C; 1 of 22 temperatures had been documented as 1.1 degrees C; and 1 of 22 temperatures had been documented as 1.4 degrees C; (c) September - 1 of 22 temperatures had been documented as 1.4 degrees C; 1 of 22 temperatures had been documented as 1.7 degrees C; and 1 of 22 temperatures had been documented as 1.1 degrees C; (d) October - 1 of 21 temperatures had been

documented as 1.8 degrees C. (4) The surveyor reviewed the records with the testing person, who stated on 02/04/2021 at 4:40 pm, the refrigerator temperatures were unacceptable for the materials as indicated above.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a review of manufacturer's instructions, records and interview with the laboratory director and testing person, the laboratory failed to establish analytical sensitivity and analytical specificity for urine drug testing for 1 of 1 analyte. Findings include: (1) On 02/04/2021, the testing person stated the following to the surveyor at 10:00 am: (a) The laboratory performed urine drug qualitative testing for Buprenorphine on the Thermofisher Indiko Plus analyzer; (b) The laboratory began performing patient urine drug testing on 01/29/2020. (2) The surveyor reviewed the performance specification records and manufacturer's instructions and identified the following: (a) CEDIA Buprenorphine Assay manufacturer's instructions stated, "The CEDIA Buprenorphine Assay is a homogenous enzyme immunoassay for qualitative or semi-quantitative determination of the presence of buprenorphine in human urine at cutoff concentration of 5 ng/ml. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine." (b) The laboratory performance specification records demonstrated accuracy, precision, reportable range, and reference range. However, the laboratory was using 20 ng/ml as the lowest cutoff value, which determined positive or negative patient results. (3) Since the laboratory had modified the manufacturer's cutoff concentration levels, the surveyor asked the laboratory director and testing person if analytical specificity and analytical sensitivity establishment studies had been performed. The laboratory director stated on 02/04/2021 at 01:10 pm analytical specificity and analytical sensitivity establishment studies had not been performed.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the testing person, the laboratory failed to ensure a patient test report included specimen information for acceptability such as, date and time of collection and date and time of receipt into the laboratory. Findings include: (1) On 02/04/2021, the testing person stated the following to the surveyor at 10:00 am: (a) The laboratory performed qualitative Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, and Oxycodone testing for urine specimens on the Thermofisher Indiko Plus analyzer; (b) The laboratory performed quantitative pH, and Specific Gravity testing for urine specimens on the Thermofisher Indiko Plus analyzer. (2) The surveyor reviewed 1 test report for a patient tested on 12/22/2020. The report did not include information regarding the condition and disposition of specimens that met the laboratory's criteria for acceptability as follows: (a) Date and time of specimen collection (b) Date and time of specimen receipt into the laboratory (3) The report was reviewed with the testing person, who stated on 02/04/2021 at 04:50 pm the patient report did not include a specimen information for acceptability as indicated above.

D5807

TEST REPORT
CFR(s): 493.1291(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 a review of a patient report and interview with the testing person, the laboratory failed to provide normal reference intervals for 1 of 1 Urine Drug Screen test report. Findings include: (1) On 02/04/2021, the testing person stated the following to the surveyor at 10:00 am: (a) The laboratory performed qualitative Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Creatinine, Methadone, Opiate, and Oxycodone testing for urine specimens on the Thermofisher Indiko Plus analyzer; (b) The laboratory performed quantitative pH, and Specific Gravity testing for urine specimens on the Thermofisher Indiko Plus analyzer. (2) The surveyor reviewed 1 test report for a patient tested on 12/22/2020. The report did not include a normal reference range for the following: (a) pH (b) Specific Gravity (3) The report was reviewed with the testing person, who stated on 02/04/2021 at 04:50 pm the patient report did not include a normal reference range as indicated above.