Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2284468	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Freeman Health Partners Medical Services, Pc	222 State Street Suite A, Dickson, TN	

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
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 laboratory observation, review of manufacturer package inserts, lack of documentation, review of procedure manual, search of the Food and Drug Administration (FDA) test database, staff interviews, and electronic mail communication, the laboratory failed to establish the acceptability of the point-of-care urine drug testing cups as an acceptable specimen type for the Thermo Scientific Indiko Plus and the Aligent 6420 Quad LC/MS toxicology platforms (Refer to D5423 Citation One), failed to establish urine specimen storage and stability requirements for toxicology tests performed on the Aligent 6420 Quad LC/MS (Refer to D5423 Citation Two), and failed to establish the performance specifications for the off-label use of urine drug screen testing cups (Refer to D5423 Citation Three).
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:
CITATION ONE: Based on observation of the laboratory, staff interview, review of manufacturer package inserts, lack of documentation, and exit interview with staff, the laboratory failed to establish the acceptability of the point-of-care urine drug testing cup as an acceptable specimen type for both the Thermo Scientific Indiko Plus and the Aligent 6420 Quad LC/MS. The findings include: 1. Observation of the laboratory on 05/06/24 at 9 a.m. revealed two instruments used for performing patient urine toxicology testing. The laboratory used the Thermo Scientific Indiko Plus to perform qualitative urine drug screens and the Agilent 6420 Triple Quad LC/MS for urine toxicology confirmation testing. 2. Observation on 05/06/24 at 11:30 a.m. of the point-of-care testing area revealed urine drug screen cup test kits used in the patient intake area. The laboratory used two brands of urine drug screen testing cups: the DTPM and the Medimpex QTest. Observation also revealed chemical reagent test strips were observed inside the urine drug screen cup testing containers. 3. The on-site testing person stated during interview on 05/06/24 at 3 p.m. that the laboratory used urine from the DTPM and Medimpex QTest urine drug screen testing cup containers for performing toxicology testing on both the Thermo Scientific Indiko Plus and the Aligent 6420 Triple Quad LC/MS. She further stated that the laboratory received and tested a 'few' specimens collected in these cups each week. 4. The manufacturer package inserts for the Thermo Scientific Indiko Plus Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Ethyl Alcohol, Methadone, and Opiate assays stated the following: "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed." 5. The laboratory had not established the acceptability of the DTMS and Medimpex QTest urine drug screening test cup containers as an acceptable specimen container type for performing toxicology tests on the Thermo Scientific Indiko Plus instrument or the Aligent 6420 Triple Quad LC /MS instrument. 6. The on-site testing person and laboratory liaison confirmed the survey findings during the interview on 05/06/24 at 3:30 p.m. CITATION TWO: Based on observation of the laboratory, review of the laboratory procedure manual, lack of documentation, staff interviews, and electronic mail communication, the laboratory failed to establish urine specimen storage and stability for the toxicology tests performed on the Aligent 6420 Quad LC/MS confirmatory toxicology test platform with approximately 1500 patients tested since patient testing began. 1. Observation of the laboratory on 05/06/24 at 9 a.m. revealed the Agilent 6420 Triple Quad LC/MS used for urine toxicology confirmation testing. 2. The laboratory's urine specimen collection procedure stated urine specimens for toxicology testing were stable for seven days refrigerated and 30 days frozen. 3. The laboratory had not completed studies establishing urine storage and stability for the toxicology tests performed on the Aligent 6420 Triple Quad LC/MS instrument. 4. The on-site testing person and laboratory liaison confirmed the survey findings on 05/06/24 at 3:30 p.m. 5. Review of an electronic mail received received from the on-site testing person on 05 /24/24 at 7:54 a.m. revealed the laboratory performed approximately 1500 patient drug screens on the Agilent 6420 LCMS since testing began. CITATION THREE: Based on observation of the laboratory, review of manufacturer package inserts, search of the FDA test complexity database, lack of documentation, and exit interviews with staff, the laboratory failed to establish the performance specifications for the use of urine drug screen test cups that were not classified by the FDA and labeled for forensic use only. The findings include: 1. Observation of the point-of-care

	testing area on 05/06/24 at 11:30 a.m. revealed the laboratory used a urine drug screening test cup. During observations, the lead testing person stated the test was used to screen 'suspicious' patients in the patient intake area. The brands noted were DTPM and Medimpex QTest. 2. A review of the manufacturer's package inserts revealed the following statement in both inserts: "For Forensic Use Only." 3. A search of the FDA database revealed the DTPM urine drug screen test cup was not listed. 4. The laboratory could not provide evidence of establishment studies for the off-label use of the DTPM and Medimpex QTest urine drug. 5. A review of final patient test reports revealed the laboratory reported screening results from the DTPM cup on patient 4125 on 05/06/24, and screening results from the Medimpex QTest cup on patient 3997 on 04/24/24. 6. The on-site testing person and laboratory liaison confirmed the survey findings during the exit interview on 05/06/24 at 3:30 p.m.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on laboratory observation, review of manufacturer package inserts, review of laboratory records, and staff interviews, testing personnel performing urine drug screening testing as a high-complexity test did not qualify as high-complexity testing personnel. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

	program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package inserts, review of laboratory records, and exit interviews with staff, five of five testing personnel that performed point-of-care urine drug testing did not qualify as high-complexity testing personnel. The findings include: 1. Observation of the point-of-care testing area on 05/06/24 at 11:30 a.m. revealed the laboratory used urine drug screening test cups. During observations, the onsite testing person stated the laboratory used the tests to screen 'suspicious' patients in the intake area and that intake personnel performed the test. The brands noted were DTPM and Medimpex QTest (Refer to D5493 Citation Number Three). 2. A review of the manufacturer's package inserts revealed the following statement in both inserts: "For Forensic Use Only." 3. Review of laboratory records revealed the following: Five personnel were trained to use the urine drug screen test cups. Records did not include evidence of the highest level of education, training and experience to qualify the testing personnel as high-complexity testing persons. 4. The onsite testing person and laboratory liaison confirmed during exit interview on 05/15/24 at 3:30 p.m. that the laboratory did not have documentation that qualified the five testing persons who performed urine drug screens on the DTPM and Medimpex QTest as high-complexity testing personnel.